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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CALIFORNIA PUBLIC EMPLOYEES' RETIREMENT SYSTEM, *Plaintiff*, v. CELGENE CORPORATION; SCOTT A. SMITH; TERRIE CURRAN; and PHILIPPE MARTIN, *Defendants*.	Civil Action No.: **COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** **DEMAND FOR JURY TRIAL**

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GLOSSARY OF TERMS

AAN	American Association of Neurology
ADME	Absorption, Distribution, Metabolism and Excretion
ARR	Annualized Relapse Rate
AUC	Area Under the Curve
BD	Business Development
CD	Crohn's Disease
CELG	Celgene ticker symbol
CFR	Code of Federal Regulations
CPMAC	Corporate Pricing and Market Access Committee
HEOR	U.S. Health Economics and Outcomes Research
I&I	Inflammation & Immunology
IBD	Inflammatory Bowel Disease
IIEC	Inflammation & Immunology Executive Committee
MS	Multiple Sclerosis
NDA	New Drug Application
NICE	National Institute for Health and Care Excellence
PA	Psoriatic Arthritis
PBM	Pharmacy Benefits Manager
RMS	Relapsing Multiple Sclerosis
RTF	Refuse To File
S1P1	sphingosine-1-phosphate receptor-1
SEC	Securities and Exchange Commission
SES-CD	Simple Endoscopic Score for Crohn's Disease
SOPP	Standard Operating Policy and Procedure
UC	Ulcerative Colitis

Plaintiff California Public Employees' Retirement System ("CalPERS" or "Plaintiff"), by and through its undersigned counsel, brings this action under the Securities Exchange Act of 1934 ("Exchange Act") against Celgene Corporation ("Celgene" or the "Company") and certain of its former officers (collectively, "Defendants") to recover damages for losses Plaintiff has suffered in connection with its purchases and acquisitions of Celgene common stock during the period September 12, 2016 to April 27, 2018, both dates inclusive (the "Relevant Period").

Plaintiff alleges the following upon personal knowledge as to itself and its own acts, and upon information and belief as to all other matters. Plaintiff's information and belief is based upon, among other things, the investigation conducted by and through its attorneys, which included, among other things, analysis of Celgene's filings with the U.S. Securities and Exchange Commission ("SEC"), wire and press releases published by Celgene, analyst reports and advisories about the Company, media reports concerning Celgene, and other publicly available information. Plaintiff's information and belief is based, in part, upon the Second Amended Class Action Complaint filed on February 27, 2019 in the class action *In re Celgene Corp. Sec. Litig.*, Case No. 18-cv-04772 (JMV) (JBC) (D.N.J.) (the "Class Complaint"), including the allegations therein based on interviews with former employees and consultants of Celgene. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. INTRODUCTION

1. By 2015, Celgene confronted a major problem. The Company knew that in just a few years, it would lose its single largest source of revenue. Celgene's blockbuster multiple myeloma drug, Revlimid, was going to lose patent exclusivity in 2022. As Celgene knew, when that happened, less expensive generic versions of Revlimid would immediately take much of the market share that had been Revlimid's alone since 2006. Celgene would no longer be able to

lean on Revlimid to provide billions in annual revenues. For more than five years running, Revlimid had delivered well over half of the net product sales for the entire Company. In 2014, net product sales from Revlimid accounted for $4.98 billion, or ***more than 65%*** of total net sales, for the Company as a whole. Revlimid accounted for 63% and 62% of total net sales in 2015 and 2016, respectively.

2. The approaching threat to Celgene from "the Revlimid patent cliff" was recognized in 2015 and throughout the Relevant Period by investment analysts and national media outlets alike. For example, in July 2015, investment analysts at Morningstar discussed the Company's need to "reduce Celgene's reliance on cancer drug Revlimid beyond 2020." Celgene's over-dependence on Revlimid continued throughout the Relevant Period, leading one analyst to write in May 2017 that "investors have reason to be 'concerned' over the Company's revenue concentration from Revlimid."

3. Celgene needed something it could point to as the replacement for its multi-billion dollar blockbuster drug. It needed a major new source for the revenue and growth that investors had come to rely on from Revlimid. Celgene knew it. The industry knew it. Investors knew it.

4. The alleged fraud in this case begins in September 2016, when Celgene embarked on a campaign to fraudulently misrepresent that two drugs in its Inflammation & Immunology ("I&I") franchise, **Otezla** and **Ozanimod**, were poised to be billion-dollar blockbusters and provide massive revenues after Revlimid went off-patent. As Defendants knew, that was nowhere near the truth.

5. When the Relevant Period began, Celgene represented that a third drug, GED-0301**,** also known as Mongersen, would—along with Otezla and Ozanimod—contribute to replacing the Revlimid revenue. Licensed from a small, Irish pharmaceutical company called

Nogra in April 2014 for an upfront $710 million payment and tiered royalties, GED-0301 was touted as a potentially transformative treatment for the difficult-to-treat inflammatory condition Crohn's Disease ("CD") in January 2015. On October 19, 2017, however, Celgene announced what investors recognized as the death knell for GED-0301.

6. The failure of GED-0301 increased the already-heightened significance of Otezla and Ozanimod. Otezla is a pill that treats psoriasis and psoriatic arthritis ("PA"), which Celgene began to sell in 2014. Celgene marketed Otezla as the first oral therapy approved by the U.S. Food and Drug Administration ("FDA") for the treatment of adults with active PA.

7. Celgene added Ozanimod, through a $7.2 billion acquisition of Receptos, Inc. ("Receptos") on July 14, 2015. Ozanimod was in development for the treatment of multiple sclerosis ("MS") and ulcerative colitis ("UC").

8. After the Receptos acquisition, on July 15, 2015, *The New York Times* reported that Celgene:

> has grown to be one of the most successful biotechnology companies, based largely on its blockbuster cancer drug, Revlimid. But Revlimid will eventually lose patent protection, and the company has been aggressively looking to expand its business and diversify. . . . Celgene executives said that ozanimod could have peak annual sales of $4 billion to $6 billion and would complement GED-0301 and also Otezla, a pill Celgene already sells to treat psoriasis and psoriatic arthritis.

9. Throughout the Relevant Period, Celgene again and again trumpeted the supposed multi-billion dollar "replacement" revenues that these two I&I drugs—Otezla and Ozanimod—would deliver in the next few years, as Revlimid fell off the "patent cliff" and its revenues faded away. Unbeknownst to the market, however, from at least 2015 until the end of the Relevant Period, Celgene and numerous Celgene executives materially misrepresented the true facts about Otezla and, starting in 2017, Ozanimod.

10. In their attempt to assure the market that Celgene could fill the revenue hole Revlimid would soon leave, Celgene and the other Defendants concealed the truth from investors at almost every turn. In particular, Defendants: (i) ignored warnings of flat sales, implacable barriers to market penetration, and explicit calls to change long-standing, publicly issued sales guidance for Otezla from Celgene's senior market access executives, and (ii) disregarded warnings and guidance from Celgene's senior scientists and its primary regulator, the FDA, confirming that the Company's publicly promised application for approval of Ozanimod by the FDA in late 2017 would be rejected without required study data. Instead, Defendants misrepresented to investors the true state of affairs surrounding the growth and development status of these drugs, no matter how bleak things appeared to those within the Company.

11. By the end of the Relevant Period, Defendants disclosed that: (i) the Company had reduced its revenue guidance for Otezla by over a quarter of a billion dollars; and (ii) the FDA issued a stunning "Refusal to File" ("RTF") rejection of Celgene's initial New Drug Application ("NDA") for Ozanimod. Defendants' fraud directly caused billions of dollars in losses to Celgene investors, including Plaintiff.

A. OTEZLA

12. On January 12, 2015, Celgene publicly unveiled a five year strategic growth plan. Celgene claimed that its I&I franchise would grow to deliver $3 billion in net sales by 2020 and that Otezla would lead the way. Specifically, Celgene stated that Otezla, which launched in 2014, would bring in $1.5 billion to $2 billion in net sales ***by 2017***.

13. On September 12, 2016, the beginning of the Relevant Period, Defendant Scott A. Smith ("Smith"), then president of Celgene's I&I franchise, affirmed these claims, stating at the Morgan Stanley Global Healthcare Conference, "[w]e believe that we should increase price ***and we've got the value and the data to support increasing utilization, and increasing value***."

14. Before and during the Relevant Period, Defendants repeated the refrain that Otezla would achieve $1.5 billion to $2 billion in revenues by 2017, signaling to the market that the conditions necessary to hit those numbers—sustained and increasing market acceptance and sales growth—were firmly in place. Those statements were materially false and misleading when made. In reality, after the initial post-release excitement in 2014, Defendants knew that Otezla sales growth was flat, and numerous factors barred the way to further market penetration for the drug.

15. For starters, Otezla was trying to take market share away from well-established, proven psoriasis and PA drugs, which doctors knew and trusted, and also faced competition from other new entrants into the space. More fundamentally, Otezla did not work as well as the other psoriasis and PA treatments, and Defendants knew it. Reports from the field did not support competitive efficacy levels. Otezla also worked more slowly, and on a narrower range of indications, than its competitors, further limiting its potential patient population. Furthermore, while Celgene promoted the fact that Otezla was an easy-to-take pill, as opposed to the inconvenient injections of its competitors, multiple former Celgene employees confirmed that its inferior efficacy overshadowed this convenience, contributing to lower prescription rates.

16. In addition, insurers and Pharmacy Benefits Managers ("PBMs"), who greatly influence whether and when treatments are covered by insurance plans, posed another major obstacle to the growth of Otezla sales. In 2015, these entities largely refused to cover Otezla as a first-line treatment. Instead, they imposed so-called "step-edits" – requirements that patients first try less expensive treatments before being covered for Otezla.

17. To get the step-edits removed and attempt to gain market share, Celgene decided to "pay to play" and offered steep discounts and rebates to insurers for Otezla. The discounts

also drove down the price that Celgene could obtain from Medicaid. The discounts, however, did not buy Celgene enough market access to offset the lower revenue generated from the discounted Otezla sales.

18. Numerous former Celgene employees reported that before and throughout the Relevant Period, these and other fundamental barriers were recognized within the Company as blocking Otezla from selling sufficiently to achieve the 2017 sales guidance, which Defendants repeatedly and unwaveringly affirmed to the public without any reasonable basis.

19. The dismal Otezla growth trends from 2015 and 2016 were recognized and discussed at the highest levels of Celgene's I&I franchise, as was the fact that ***the publicly-issued 2017 net sales guidance for Otezla could not be met***. Indeed, former high-ranking Celgene employees specifically recounted that at multiple meetings of Celgene's I&I Executive Committee ("IIEC"), of which Defendants Curran and Smith were members, in the third and fourth quarters of 2016, senior market access executives presented Otezla data and warned expressly that the 2017 net sales guidance for Otezla was not attainable.

20. By the fourth quarter of 2016, high-ranking Celgene employees, including Robert Tessarolo, the Senior Vice President of I&I, U.S., explicitly urged Curran, Smith, and the other members of the IIEC to lower the guidance. Despite the fact that, according to a senior executive in the U.S. Market Access group, "***everyone knew that the actual stated forecast was not reasonable***" and could not be met, the IIEC insisted that the public guidance would not be changed.[1] Indeed, this executive recounts that Defendants Smith and Curran "told" the forecasting team to ***"change" the numbers***—i.e., Celgene's internal forecasts—to make Otezla's

[1] Unless otherwise noted, all emphasis is added.

sales growth appear better than it actually was. Moreover, Defendants continued to publicly reaffirm the guidance through the end of 2016, without any reasonable basis.

21. In a public filing in January 2017, Celgene represented that it expected Otezla to achieve approximately 57% year-over-year sales growth to meet its 2017 guidance. Former Celgene personnel recount, however, that by early 2017, it was again recognized and openly discussed by senior market access employees within the Company that there was no way 57% growth in Otezla sales was attainable in 2017.

22. Moreover, the IIEC was once again warned, in at least one meeting in early 2017, that the Otezla net sales guidance remained too high, was unattainable, and needed to be lowered. In response, Defendant Smith cut off the presentation, saying he had heard enough.

23. After Defendants continued to falsely affirm the 2017 Otezla net sales guidance throughout the second and third quarters of 2017, on October 26, 2017, Celgene abruptly reversed course and admitted publicly that Otezla would not hit the net sales guidance the Company had long affirmed, and cut its Otezla guidance by a ***quarter of a billion dollars***. This disclosure blindsided investment analysts, and the market reeled in response to the news, with the price of Celgene's common stock ***falling $19.57***, or more than ***16% per share***, on October 26, 2017 alone.

B. OZANIMOD

24. Defendants also fraudulently misrepresented the true facts about Ozanimod, when, starting in January 2017, they represented that this development-stage MS and UC drug

was sailing towards regulatory approval (and subsequent product launch) in late 2017, based on successful, ongoing Phase III clinical testing.[2]

25. In reality, in late 2016, Celgene had received results from Ozanimod tests (which Celgene had long deferred performing) that identified critical issues in areas known to be of high FDA concern. These test results were a huge setback for Ozanimod. They raised basic questions about how the drug worked in humans that would require many months, and even years, of additional testing to answer. The results virtually guaranteed that the FDA would not accept, much less approve, an Ozanimod NDA in 2017 as the Company had represented to investors. In a private meeting, the FDA told Celgene that further testing was required with the Ozanimod NDA. Yet Celgene said nothing to the market and, instead, pushed forward with the doomed Ozanimod NDA in late 2017, without the additional test results. The FDA promptly rejected the NDA, revealing Defendants' fraud to a stunned marketplace.

26. Celgene acquired Ozanimod in July 2015, when it bought Receptos, the company that first developed the drug. Strong results from advanced clinical studies made Ozanimod the "crown jewel" of the $7.2 billion acquisition, and Celgene immediately projected FDA approval and launch by 2018, and potential Ozanimod sales of up to $6 billion per year. Post-acquisition,

[2] New drugs undergo three phases of pre-approval studies. During Phase I studies, researchers test the new drug in 20 to 80 healthy volunteers. For safety and adjust dosing amounts to find the highest dose of the new treatment that can be given safely without serious side effects. During Phase II studies, researchers administer the new drug to a group of patients with the disease or condition for which the drug is being developed ***to test if the drug works***, while continuing to collect safety information. Phase III studies ***presume that the drug has an effect***, and are designed to assess the safety and effectiveness of the new treatment in a larger population over a longer period of time (and therefore its value in clinical practice). Phase III studies are typically randomized controlled multi-center trials on large patient groups (300-3,000 or more depending on the disease/medical condition being studied) and are aimed at providing a definitive assessment if how effective the drug is, in comparison with current "gold standard" treatment.

Celgene took complete control of Receptos, installing Defendant Philippe Martin (Celgene's Vice President of Leadership & Project Management – Immunology) as *de facto* CEO.

27. If Ozanimod won FDA approval, it would compete directly with the established MS drug, Gilenya. Just three months after Celgene bought Ozanimod, however, a major patent ruling against Gilenya fundamentally changed the market outlook. In October 2015, Gilenya lost a challenge to would-be generics. Cheap, generic versions of Gilenya would thus hit the market by 2019. This ramped up the pressure on Celgene to establish Ozanimod's market share well before 2019, when competition from Gilenya generics would kick in.

28. In 2015, Celgene repeatedly told the market that Phase III trials for Ozanimod were well underway, and that the drug was on track for submission for FDA approval (for MS indications) by 2017, and a projected launch by 2018. Analysts cheered Ozanimod's progress toward launch, with RBC Capital Markets analysts, for example, reporting that Ozanimod was "ahead in timing," as of November 2015. The Gilenya generics ruling left little margin for error.

29. However, through 2015 and much of 2016, Celgene's Ozanimod development portfolio was missing a crucial component. Namely, Celgene lacked complete and adequate testing of Ozanimod's metabolites. Metabolites are essentially the chemical byproducts of the body breaking down a drug. They can be inactive or active. Active metabolites produce their own effects on the body and can impact the functioning of drugs. New Drug Applications must address drug metabolism, and in guidance dating back to at least 2008, the FDA has made clear that testing and understanding the properties of active metabolites associated with a drug is a priority that should be undertaken "as early as possible" in drug development. The FDA warns that a failure to ascertain metabolite effects can "cause development and marketing delays." Seminal drug development literature also urges that the importance of metabolite testing "cannot

be overemphasized," and that it should be done "at an early stage of clinical development, such that issues of disproportionate human metabolites may be addressed ***prior to the initiation of large-scale clinical trials***."

30. Nevertheless, Celgene had pushed forward with large scale Phase III clinical trials of Ozanimod without the requisite metabolite testing. The Company had put off performing (among other tests) the critical test to conclusively identify all active metabolites and begin to study how these metabolites affected the body—the "human radiolabeled mass balance study," which is "generally accepted" in the field as the "gold standard." Working, in effect, out of order, Celgene sought to backfill clinical pharmacology testing of Ozanimod (including metabolite testing) only ***after*** it had publicized promising results from the efficacy phases of the drug's development.

31. Celgene did not begin the necessary "mass balance" testing for Ozanimod metabolites until October 2016, more than a year after Celgene acquired Ozanimod. Unbeknownst to investors, this testing detected the disproportionate presence of a highly active metabolite, named CC112273 by Celgene (the "Metabolite"). Under FDA guidance, various forms of significant, additional testing on the Metabolite were required before submitting the Ozanimod NDA. Those tests, however, would take time.

32. These late metabolite test results, obtained in November 2016, sent shockwaves through Celgene. Defendant Martin and other Celgene senior management knew about the results and regularly received updates on the issue. Former employees with roles in the Ozanimod development process immediately recognized the need for additional testing on the Metabolite before an Ozanimod NDA could be filed with the FDA. These former employees noted that filing the NDA without the testing would cause the FDA to issue an RTF letter, which is a rejection of

the NDA as facially deficient, a fact that was conveyed to their direct management. One former clinical pharmacologist who had first-hand knowledge of the discovery of the Metabolite stated that ***the working team in "clinpharm" advocated that if Celgene submitted the NDA, it would get a refusal to file, and he thought other teams felt that way too from speaking with them***. A second former employee also recounted that the need for additional testing was raised in a meeting involving Celgene senior leaders, including Tran and Defendant Martin, in early 2017. However, Martin abruptly shut down the discussion.

33. Notwithstanding the discovery of the Metabolite in November 2016 and the need to conduct protracted additional ***Phase I*** testing, Defendants knowingly misrepresented that that Ozanimod was advancing through Phase III testing, and that, "contingent on that, we will file an NDA for Ozanimod in multiple sclerosis by the end of the year." And when the last Phase III trial was ultimately completed in the spring of 2017, Defendants touted the results, without ever mentioning the need to go back and perform basic Phase I testing on the Metabolite. In essence, Defendants told investors that Ozanimod was on the two-yard line for NDA submission when, ***in fact***, given the need to conduct the additional testing, it was back at the fifty-yard line.

34. This reflected that, according to a former Celgene employee, by March or April of 2017, an internal push had arisen to promote Ozanimod as a potential therapy for CD. Though Celgene had consistently touted GED-0301 as Celgene's CD treatment, "frantic" efforts ensued within Celgene to show better results for Ozanimod in treating CD than those shown by GED-0301. In at least one instance, employees were directed to manipulate testing parameters to make Ozanimod look better than GED-0301 as a CD treatment.

35. Analysts relied upon on Defendants' misrepresentations. For example, in a January 2017 report, J.P. Morgan analysts wrote that an Ozanimod "NDA submission" by year-end 2017 was a "Key 2017 catalyst" for Celgene.

36. Former Celgene employees also recounted that Celgene met with the FDA in November 2017 to discuss the Ozanimod NDA and ***the FDA explicitly informed Celgene that the Metabolite test results must be included in any Ozanimod NDA***. Despite this directive from the FDA, Defendants charged ahead and filed the deficient Ozanimod NDA in December 2017. This was a reckless gamble that was also financially motivated. Former Celgene employees report that Defendant Martin and other executives received lucrative bonuses upon mere submission of the NDA to the FDA, and that they "***just wanted to get the NDA out the door***." Furthermore, as noted above, Celgene was desperate to capture market share from Gilenya before it lost patent exclusivity in 2019, and delaying submission of the NDA to complete protracted testing of the Metabolite would prevent Ozanimod's launch until after the market was saturated with cheaper generic alternatives.

37. Celgene did not inform the market of the demise of GED-0301 until it could present good news, to try to drown out the bad. To that end, on October 16, 2017, Celgene issued a press release stating that Phase II studies of ***Ozanimod*** showed "meaningful clinical and endoscopic improvements in patients with . . . Crohn's disease."

38. Three days later, on October 19, 2017, Celgene announced that GED-0301 had exhibited futility—i.e., there was no evidence that it worked—and the Phase III trial was discontinued. This further increased the pressure to show that Ozanimod could pull its weight in navigating the Revlimid patent cliff, and Defendants continued to falsely and misleadingly

represent the status of the Ozanimod NDA application and omit the existence and import of the Metabolite.

39. On February 27, 2018, Celgene shocked the market when it disclosed that it had received an RTF rejection of its Ozanimod NDA application from the FDA, just as Celgene employees had warned. Celgene disclosed that, "[u]pon its preliminary review, the FDA determined that the . . . pharmacology sections of the NDA were insufficient to permit a complete review." The FDA issues an RTF only where an NDA contains glaring, facial deficiencies, including "***scientific incompleteness, such as omission of critical data, information or analyses needed to evaluate safety, purity or potency***." Notably, RTFs are exceedingly rare—industry observers estimate that RTFs have been issued just forty-five times in the past ***sixteen years***, and almost never to well-established pharmaceutical companies like Celgene.

40. Celgene's receipt of the RTF was a public debacle. Investment analysts decried Celgene's "self-inflicted wounds" and lashed the Company with criticism. When the dust settled on the February 27, 2018 disclosure, it had driven Celgene's common stock price down by $8.66 per share in a single day.

41. In late April 2018, Celgene disclosed additional information about the Metabolite. Based on this presentation, analysts from Morgan Stanley reported that completion of the required metabolite testing would delay the refiling of the Ozanimod NDA by ***up to three years***, or until 2021. In direct response to this final disclosure, which concludes the alleged Relevant Period, Celgene's common stock price fell an additional $4.08 on heavy trading.

II. JURISDICTION AND VENUE

42. The claims asserted herein arise under Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. § 78j(b), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. § 240.10b-5.

43. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and under 28 U.S.C. § 1331, because this is a civil action arising under the laws of the United States.

44. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b), because Defendant Celgene conducts business in this District and also maintains its administrative headquarters in this District.

45. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications, and the facilities of the national securities exchange.

III. PARTIES

A. PLAINTIFF

46. Plaintiff California Public Employees' Retirement System is an agency of the California government and offers a defined benefit retirement plan for California public employees, retirees, and their families. CalPERS manages the largest public pension fund in the United States. Its headquarters are located in Sacramento, and it maintains eight regional offices throughout California. CalPERS purchased Celgene common stock during the Relevant Period, as set forth in Appendix A, and suffered substantial losses as a result of the conduct complained of herein.

B. DEFENDANTS

1. Celgene

47. Defendant Celgene, a Delaware corporation headquartered in Summit, New Jersey, is an integrated global biopharmaceutical company engaged primarily in the discovery, development, and commercialization of therapies for the treatment of cancer and inflammatory diseases. The Company operates two key divisions: (i) the I&I franchise, which focuses on developing drugs for treatment of inflammatory diseases, such as psoriasis, PA, UC, MS, and CD; and (ii) the "Hematology & Oncology" franchise, which focuses on developing treatments for blood diseases and cancer. Celgene's common stock trades on the NASDAQ Global Select Market under the ticker symbol "CELG." For fiscal year 2017, Celgene reported earnings of $2.539 billion with annual revenues of $13 billion.

48. On July 15, 2015, Celgene entered into an agreement and plan of merger with Receptos, a San Diego, California-based biopharmaceutical company, pursuant to which Celgene acquired Receptos and its development-stage drug, Ozanimod, through a series of merger transactions for $7.2 billion. On August 27, 2015, Celgene closed its acquisition of Receptos, which resulted in Receptos becoming a wholly-owned subsidiary of Celgene.

2. The Individual Defendants

49. Defendant Scott A. Smith ("Smith") served as Celgene's President and COO from April 1, 2017 until his departure from Celgene, on April 2, 2018. Prior to April 1, 2017, Smith was President of the I&I franchise. According to the Company's 2017 Proxy Statement, in this role, Smith was engaged in company-wide strategic planning and decision making aimed at delivering on short and long-term financial goals and continuing to innovate, develop, and commercialize Celgene's products. Smith also oversaw the clinical development, global registration, and commercial sales of drugs within the I&I franchise.

50. Defendant Terrie Curran ("Curran") was promoted to President of Celgene's Global I&I franchise on April 1, 2017. From March 2016 through April 1, 2017, Curran served as Head of Worldwide Markets for Celgene's I&I franchise. From April 2013 to March 2016, Curran served as the U.S. Commercial Head of the I&I franchise. According to Celgene's Senior Management Team biographies, in this role, Curran built capabilities and recruited the teams that executed the U.S. launch of Otezla. Curran left Celgene in December 2019.

51. Defendant Philippe Martin ("Martin") served as Celgene's Vice President of Leadership & Project Management – Immunology beginning in January 2014. Martin also served as Celgene's Corporate Vice President from January 2017 to June 2018. From June 2016 to June 2018, Martin also served as Managing Director at Celgene-Receptos. Martin left Celgene in June 2018.

52. Defendants Smith, Curran, and Martin are referred to herein as the "Individual Defendants."

C. RELEVANT NON-PARTIES

1. Additional Directors and Officers

53. Mark J. Alles ("Alles") served as Celgene's Chief Executive Officer ("CEO") beginning March 1, 2016, and as Chairman of its Board of Directors beginning February 6, 2018. He left the Company at the end of 2019. According to the Company's 2017 Annual Report, as CEO, Alles was the chief operating decision maker, and managed and allocated resources at the global corporate level. As discussed in the Company's April 30, 2018 Proxy Statement, at the beginning of each fiscal year, Alles established goals and objectives with each executive officer that were designed to advance his or her functional role, while promoting achievement of overall corporate performance goals. From August 2014 until February 2016, Alles served as Celgene's Executive Vice President and Chief Operating Officer ("COO"). Alles was elected to Celgene's

Board of Directors in February 2016, prior to which he served for over fourteen years in other senior executive positions at Celgene.

54. Robert J. Hugin ("Hugin") was Executive Chairman of Celgene's Board of Directors from March 1, 2016 until his retirement on February 5, 2018. Prior to that time, from June 2011 until March 1, 2016, Hugin served as Chairman of Celgene's Board of Directors. Hugin also served as CEO from June 16, 2010 until March 1, 2016. According to the Company's 2015 Proxy Statement, as CEO, Hugin was responsible for creating, implementing, and integrating the strategic plans for both of Celgene's franchises.

55. Peter N. Kellogg ("Kellogg") served as Celgene's Executive Vice President and Chief Corporate Strategy Officer until his retirement in mid-2019. Kellogg previously served as Celgene's Chief Financial Officer ("CFO"), and Chief Accounting Officer from August 2014 until August 2018. Kellogg joined Celgene as Executive Vice President in July 2014.

56. Jacqualyn A. Fouse ("Fouse") served as the Strategic Advisor to the Celgene Management Executive Committee beginning on April 1, 2017 and retired from Celgene effective June 30, 2017. Prior to assuming this role, from March 2016 through March 2017, Fouse served as the President and COO of Celgene. Fouse was also the President of the Hematology & Oncology franchise from August 2014 through February 2016, and was elected as a member of Celgene's Board of Directors effective February 11, 2016.

57. Nadim Ahmed ("Ahmed") was promoted to President of Celgene's Hematology & Oncology franchise on August 23, 2017. Since the merger of Celgene with Bristol Myers Squibb Co. in November 2019, Ahmed has served as the President of Hematology at the combined company. From March 2016 to August 23, 2017, Ahmed served as President of

Worldwide Markets for Hematology & Oncology. From August 2014 until March 2016, Ahmed served as General Manager of the U.S. Hematology & Oncology franchise.

58. Jonathan Q. Tran ("Tran") has served as the Executive Director of Clinical Pharmacology at Receptos since its purchase by Celgene in July 2015.

2. Former Employees, Consultants and Scientists[3]

59. FE 2 worked in Clinical Research & Development in the Company's I&I franchise from before January 12, 2015 until late 2016 in Summit, New Jersey. FE 2's responsibilities included long-term planning of both organizational and project-related activities, and assisting the Vice President of the I&I Clinical Research and Development department with the management of the department. Additionally, FE 2 participated in clinical development planning for I&I's compounds and managed departmental activities to ensure on-time delivery of the clinical component for regulatory submissions. FE 2 also served as a member of the GED-0301 developmental team and participated in writing a protocol for one of the GED-0301 studies. Prior to his work with GED-0301, FE 2 worked on over five NDAs for various drugs.

60. FE 5 was employed as a Director at Receptos from mid-2015 to mid-2017. While at Receptos, FE 5 oversaw and performed statistical analyses for the Ozanimod CD and UC studies. In this role, FE 5 was a regular attendee at meetings related to Celgene's Ozanimod clinical trials, including meetings regarding the submission of Ozanimod for FDA approval as a treatment for Relapsing Multiple Sclerosis ("RMS"). FE 5 also reviewed the GED-0301 Phase Ib study results in connection with his work on Ozanimod. While at Receptos, FE 5 reported to

[3] Former Employees, Consultants and Scientists ("FEs") will be identified herein by the number (FE 2, FE 5, etc.) used to identify them in the Class Complaint. Regardless of gender, all FEs will be described in the masculine to protect their identities.

Jeff Kopicko ("Kopicko"), the Executive Director of Biometrics. Kopicko reported to Defendant Martin, who in turn, reported to Defendant Smith.

61. FE 7 was a Senior National Account Manager at Celgene from 2013 to 2016. FE 7's work encompassed Market Access, in which he had 18 years of experience. FE 7 advised Celgene's senior executives on the pricing strategy and market access strategy for Otezla. These senior executives included Sal Grausso ("Grausso"), Executive Director of Market Access for I&I, Betty Jean Swartz ("Swartz"), Vice President of U.S. Market Access, Robert Tessarolo ("Tessarolo"), Senior Vice President of I&I, U.S., Gordon Willcox ("Willcox"), Vice President of Market Access, and Defendant Curran. In his role as Senior National Account Manager, FE 7 reported to Defendant Curran and Grausso, who in turn reported to Defendant Smith.

62. FE 8 was an I&I Sales Representative at Celgene from before January 12, 2015 to late 2017 in the Northeast Region and his focus was on selling Otezla.

63. FE 9 was a Dermatology Specialty Sales Territory Manager at Celgene from before January 12, 2015 to early 2017 in the Southwest Region and his focus was on selling Otezla. He was also involved in Celgene's launch of Otezla.

64. FE 10 worked as a Rheumatoid Sales Specialist for Celgene from early 2015 to late 2016. FE 10 was responsible for Otezla sales in the Northeast Region.

65. FE 11 was a Celgene District Sales Manager for the Northeast Region from before January 12, 2015 to late 2016. As District Sales Manager, he received weekly reports regarding Otezla sales volume and growth for the previous week, quarter, and half-year, and a year-over-year comparison. FE 11 had eleven Otezla sales representatives under his supervision – five rheumatoid representatives and six dermatology representatives.

66. FE 12 was a Sales Representative for Celgene from before January 12, 2015 to late 2017. FE 12 was responsible for Otezla sales in the Northeast Region.

67. FE 13 was a Regional Sales Manager at Celgene from before January 12, 2015 until later in early 2015. FE 13 was in charge of I&I sales for more than five states in the mid- and western U.S. FE 13 was responsible for the launch and sales of Otezla.

68. FE 14 was a Sales Representative at Celgene from before January 12, 2015 to early 2017. FE 14 promoted Otezla to doctors in a large Northeast market, from the early days of Otezla's launch until he left Celgene. At least quarterly, FE 14 received a ranking report, which force ranked FE 14 against other Otezla sales personnel based on their volume of Otezla sales.

69. FE 15 was a senior member of the Pricing and Market Access group at Celgene from before January 12, 2015 to late 2015. In this role, FE 15 developed market access models for various drugs, including Otezla. These models were based on the drug's efficacy compared to other medications already in the market space. FE 15 provided the models to Frank Zhang ("Zhang"), Celgene's Global Head of U.S. Health Economics and Outcomes Research ("HEOR"), who reported to Defendant Smith.

70. FE 16 was a high-ranking member of HEOR and Pricing for the U.K. and Ireland at Celgene from before January 12, 2015 and throughout the Relevant Period. In this role, FE 16 was responsible for making reimbursement submissions to the National Institute for Health and Care Excellence ("NICE"), an organization in the U.K. that determines whether the government will reimburse a company for a new drug. FE 16 reported to the Head of Market Access and Corporate Affairs for the U.K. and Ireland, the Global Head of HEOR and Pricing for I&I in the

U.S., who reported to Defendant Smith, and a high-ranking member of the Global Market Access group.

71. FE 17 was a senior executive in the U.S. Market Access group at Celgene from early 2016 to late 2017. In this role, FE 17 worked with the managed care team where he negotiated new contracts with health plans. FE 17 led the U.S. Market Access team responsible for optimal patient access, strategic development, and execution of Celgene's value proposition. FE 17 also prepared pricing recommendations for the IIEC, which included pricing recommendations for Otezla. FE 17 reported to Tessarolo. Tessarolo reported to Defendant Smith and Defendant Curran.

72. FE 18 was a senior executive in the HEOR group at Celgene from before January 12, 2015 until early 2018. FE 18 reported to Swartz.

73. FE 19 was a senior executive in U.S. Field HEOR from mid-2016 through the end of the Relevant Period. FE 19 worked in external Market Access to guide key decision makers with respect to patient access to specific drugs and services, efficacy, and safety. FE 19 reported up through the Executive Director of U.S. HEOR.

74. FE 20 was a senior executive in Clinical Development at Receptos from before January 12, 2015 to late 2016. FE 20 was responsible for conducting all the Phase II and Phase III studies for Ozanimod in MS and UC.

75. FE 21 was a Clinical Pharmacologist from late 2016 to early 2018 at Receptos and worked on the Phase I studies of Ozanimod. FE 21 contributed to the clinical pharmacology section of the Ozanimod NDA and had first-hand knowledge of the Metabolite starting at the time of its discovery. Following this discovery, FE 21 worked on studies regarding the Metabolite, including tests to identify and characterize the Metabolite.

76. FE 22 was a contractor for Receptos and worked as a Project Manager for the Ozanimod UC/CD team in San Diego between late 2017 and early 2018. As a Project Manager, FE 22 oversaw the Ozanimod UC/CD drug development through various clinical stages. FE 22's job responsibilities also required him to be kept apprised of the status of the MS Ozanimod project.

IV. FACTUAL ALLEGATIONS

A. CELGENE NEEDED TO OFFSET THE LOOMING LOSS OF REVLIMID'S PATENT PROTECTION

77. After the launch of Revlimid in 2006, the drug quickly became a blockbuster for Celgene. By 2010, Revlimid accounted for ***$2.469 billion*** in annual product sales (roughly ***70.4%*** of Celgene's total annual net product sales) and, by the end of 2014, Revlimid accounted for ***$4.980 billion*** in sales, representing more than 65% of Celgene's total net sales. Revlimid accounted for 63% and 62% of Celgene's total net sales in 2015 and 2016, respectively.

78. Celgene's over-reliance placed significant pressure on the Company to diversify its pipeline away from Revlimid. Indeed, analysts often cited the risk inherent in Celgene's financial success being tied so closely to a single drug. On May 5, 2017, for example, Benzinga reported that "investors have reason to be 'concerned' over the company's revenue concentration from Revlimid. . . . During the recent quarter, sales of Revlimid accounted for 64 percent of total revenue and that proportion is only growing."

79. The Revlimid patent protects the drug from generic competition, but only until the year 2022. With Revlimid's patent expiration on the horizon, and given the frequent challenges to the validity of the patent by a number of generic drug manufacturers, Celgene was under intense pressure before and during the Relevant Period to create and maintain a drug pipeline

(including through acquisitions) to offset the anticipated loss in revenues that would result from generic Revlimid competitors entering the market.

80. For example, on July 15, 2015, *The New York Times* recognized Celgene's need to replace the revenue it historically relied upon from Revlimid in an article discussing Celgene's recent acquisition of Receptos:

> Celgene agreed on Tuesday to pay $7.2 billion in cash to acquire Receptos, which is developing a potentially promising drug for autoimmune diseases. . . . Receptos, based in San Diego, is developing a drug called ozanimod that is now in late-stage clinical trials as a treatment for multiple sclerosis and ulcerative colitis, with an approval possible for multiple sclerosis as early as 2018 and for ulcerative colitis the year after. . . .
>
> [Celgene] has grown to be one of the most successful biotechnology companies, based largely on its blockbuster cancer drug, Revlimid. ***But Revlimid will eventually lose patent protection, and the company has been aggressively looking to expand its business and diversify***. . . .
>
> Celgene has earned a reputation as willing to pay top dollar either to acquire smaller companies or to license their drugs. . . . Last year it made an eye-popping initial payment of $710 million to an obscure company based in Dublin, Nogra Pharma, for rights to GED-0301, a drug being tested for Crohn's disease, which, like ulcerative colitis, is an inflammation of the bowel. . . .
>
> Celgene will be paying more than 16 times the $14 price at which Receptos went public two years ago. Celgene executives said that ozanimod could have peak annual sales of $4 billion to $6 billion and would complement GED-0301 and also Otezla, a pill Celgene already sells to treat psoriasis and psoriatic arthritis.

81. Celgene itself also told the market that it was diversifying its pipeline away from Revlimid and situating itself to offset the anticipated loss of Revlimid patent exclusivity and the accompanying reduction in revenues with the Company's I&I franchise. On May 31, 2017, for example, Alles, after referencing the Company's historical reliance on annual Revlimid revenues, told investors that GED-0301, Ozanimod and Otezla, would serve as a "replacement for it."

82. Celgene made its first foray into the IBD market through its multi-billion dollar acquisition of the rights to development-stage drug GED-0301, also known as Mongersen.

83. IBD is a term used to describe two similar disorders that involve chronic inflammation of the digestive tract: CD and UC.[4] According to the Centers for Disease Control and Prevention, an estimated 3.1 million people in the U.S. were diagnosed either with CD or UC in 2015.

84. In addition to anti-inflammatory drugs, the primary treatments for both CD and UC are immunosuppressive therapies, which inhibit patients' inflammatory response, thereby allowing for healing of the ulcers that accompany CD and UC. Two of the leading drugs—AbbVie's Humira (adalimumab), which has been available to treat PA since 2005, CD since 2007, psoriasis since 2008, and UC since 2012, and Johnson & Johnson's Remicade (infliximab), which has been available to treat CD since 1998, UC and PA since 2005, and psoriasis since 2006—are so-called "biologic" therapies that work by neutralizing a protein produced by the immune system. Each generated billions of dollars per year in sales during the Class Period. However, biologic treatments carry well-known drawbacks. They are administered only through injection and carry an increased risk of infection, among other side effects. Moreover, while biologic therapies such as Humira and Remicade have proven effective in relieving some patients' symptoms, they are not effective in as many as one-third of IBD patients.

85. By contrast, Celgene heralded GED-0301 as an oral medication, with a different mechanism of action[5] than the biologics, and which targeted the root cause of IBD while potentially avoiding the side effects associated with Remicade and Humira. Celgene claimed that GED-0301 offered a potential new path to break into the lucrative IBD market.

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[4] Crohn's Disease is characterized by relapsing inflammation leading to ulcers in the ileum and colon. Ulcerative Colitis is characterized by long-lasting ulcers in the innermost lining of the colon and rectum.

[5] "Mechanism of action" refers to the biological process through which a drug produces its effect in a patient's body.

86. On April 24, 2014, Celgene announced that it had entered into a global, royalty-bearing license agreement with Nogra Pharma Limited, a private pharmaceutical company based in Dublin, Ireland, to develop and commercialize GED-0301 for the treatment of CD and UC. As part of the deal, Celgene paid $710 million upfront and committed to almost $2 billion in additional payments based on the achievement of certain development, regulatory and sales milestones, as well as tiered royalties on sales of licensed products. The $710 million Celgene paid was the largest upfront payment any drug company had ever made to acquire a single drug.

87. In announcing the deal, Celgene described GED-0301 as "an oral antisense DNA oligonucleotide targeting Smad7 mRNA for the treatment of moderate-to-severe Crohn's disease and other indications." Whereas biologic therapies suppress the body's immune response to control inflammation, antisense therapies such as GED-0301 are supposed to work by shutting down the genes that cause diseases by binding to messenger RNA (mRNA), which is genetic material involved in the body's production of proteins.

88. In an April 24, 2014 press release, Defendant Smith, then Celgene's Senior Vice President and Global Head of I&I, stated that "GED-0301 is a potentially transformative therapy that ***demonstrated striking clinical activity in a phase II trial for Crohn's disease***." Smith added that the acquisition "strengthens our expanding pipeline of novel therapies intended to address significant unmet medical need in immune-mediated diseases." In a conference call that same day, Celgene representatives, including Defendant Smith, presented slides that, *inter alia*, claimed that the acquisition of GED-0301 "meaningfully diversifie[d] portfolio revenue in 2019-2020 and beyond."

89. However, it became clear internally that GED-0301 lacked efficacy and was a dead end. On October 19, 2017, after the market closed, Celgene announced that it was discontinuing the GED-0301 Phase III "Revolve" trial (and the related "Sustain" extension trial).

90. Though the October 19, 2017 press release stated that Celgene was waiting to review the full dataset from the Phase II trial of GED-0301 in UC to determine next steps, analysts recognized that the announcement meant that GED-0301 was a failure. For example, Mizuho Securities USA analyst Salim Syed stated that "GED-301 for all practical purposes is ***dead***."

91. This increased the pressure on Defendants to frame Otezla and Ozanimod as blockbuster drugs that would replace the Company's Revlimid revenue. Indeed, Celgene did not announce the discontinuation of the GED-0301 Phase III trial until three days after issuing, on October 16, 2017, a press release stating that Phase II studies of ***Ozanimod*** showed "meaningful clinical and endoscopic improvements in patients with . . . Crohn's disease." So, market commentary stated that investors were then expecting Celgene's anticipated submission and approval of its Ozanimod NDA to compensate for any losses or setbacks the Company suffered as a result of the GED-0301 news. For example, Raymond James reported on October 19, 2017 that it believed the failure of GED-0301 could be offset by the potential future success of Ozanimod and Otezla, writing that [m]anagement has sought to develop a continuum of inflammatory bowel disease products, and that strategy remains intact with ozanimod and Otezla." The same day, RBC Capital Markets similarly reported that "0301/mongersen d/c [discontinuation] is disappointing given high potential opportunity in Crohns for unique oral, and increases onus on ozanimod/BD [business development] for post-Revlimid revenue sustainability."

B. DEFENDANTS FRAUDULENTLY REAFFIRM OTEZLA SALES GUIDANCE THAT THEY KNEW WAS UNATTAINABLE

92. The second aspect of Defendants' three-pronged plan to replace the Company's revenue stream from Revlimid was Otezla, the most commercially advanced drug in Celgene's I&I franchise. Otezla, which the Company touted as one of its "primary commercial stage products," is an oral medication that is used to treat PA and psoriasis.[6] While many drugs used for the treatment of psoriasis and PA are biologics, Otezla is an oral medication. Celgene regularly promoted the convenience of Otezla to patients, emphasizing that Otezla is "not an injection, cream or biologic. It's a pill . . . ."

93. Otezla was approved by the FDA in March 2014 for the treatment of PA, and Celgene began recognizing revenue from the sales of Otezla during the second quarter of 2014. As early as January 13, 2014, months before the Otezla launch, Defendants primed the market that Otezla sales were poised to sky-rocket, representing that Otezla net product sales would reach $1.5 billion to $2 billion by 2017.

1. Celgene Issues 2017 Guidance for Otezla Without a Reasonable Basis

94. On January 12, 2015, Celgene issued a press release unveiling the Company's five-year strategic growth plan. According to this plan, Celgene maintained that Otezla net product sales would grow to between $1.5 billion and $2 billion in 2017 and its net product sales from the I&I franchise as a whole would exceed $3 billion by 2020. During a presentation at the J.P. Morgan Healthcare Conference that same day, Hugin highlighted the Company's 2017 Otezla sales guidance, claiming that "the progress achieved in the fourth quarter [of 2014] with

[6] Psoriatic arthritis is a type of arthritis that affects some people who have psoriasis, a chronic skin condition that speeds up the life cycle of skin cells, causing extra skin cells to build up on the surface of the skin in scales and red patches that are itchy and sometimes painful.

Otezla in our I&I franchise, gives us great confidence that we are on track to really again meet or exceed the 2017 guidance."

2. Celgene Internally Recognizes Multiple Barriers that Prevented Otezla From Achieving the 2017 Otezla Sales Guidance

95. Unbeknownst to investors, Defendants lacked a reasonable basis for their January 2015 statements reaffirming the Company's aggressive 2017 sales guidance for Otezla. In reality, after the 2014 launch, numerous barriers impeded Celgene from achieving those numbers, and Company sales representatives struggled and failed to grow their Otezla sales commensurate with the Company's projections.

96. According to FE 7, a Senior National Account Manager, as early as the March 2014 launch, Otezla's sales and revenue generating capabilities were severely impaired by several dynamics.

97. For example, FE 7 stated that, shortly after the drug's launch in 2014, Celgene offered excessive rebates and discounts to convince insurance companies to remove "step-edits" – the requirements put in place by insurers and PBMs that forced patients to try other, less expensive therapies before being permitted to use Otezla. Celgene's goal was to gain market share for Otezla by using the rebates and discounts to lower Otezla's effective. However, according to FE 7, the plan was doomed from inception.

98. As FE 7 explained, one consequence of the Company's steep rebates and discounts on Otezla was additional downward pressure on Otezla sales revenues due to the impact of these rebates and discounts on Celgene's "best price calculation" for the drug. As FE 7 explained, rather than boosting net sales from Otezla by capturing market share through the large discounts and rebates, Celgene drove down the "best price" calculation, and was left selling

the drug for what FE 7 illustratively described as one cent per pill, thus ensuring that the Company would never meet the 2017 Otezla net sales guidance.

99. In the pharmaceutical industry, a drug's "best price" refers to the price a drug manufacturer must offer to Medicaid. Specifically, the Medicaid "best price" policy requires drug manufacturers by statute to give Medicaid programs the lowest or "best" price offered to nearly all purchasers. Accordingly, because Celgene was repeatedly driving down the price of Otezla that it was offering to insurers and PBMs, it necessarily drove down the price it was required to provide to one if its largest payers, Medicaid.

100. The inherent flaw of this strategy was known to senior management, including Defendant Smith, who FE 7 stated had the final say with regard to Otezla and Market Access decisions. In fact, starting in 2014, FE 7 repeatedly warned Smith that the Company's pricing and discounting strategy for Otezla was fatally flawed and simply would not work to increase revenues. When Otezla launched, FE 7 informed Smith that he would be destroying the "best price" for the drug by offering large rebates and discounts, thereby setting Otezla up for consistently depressed net sales going forward. In response, Smith told FE 7 that Celgene would do "whatever it takes to get the business."

101. After the Otezla launch in 2014, FE 7 wrote multiple emails to Celgene's senior executive management, including Smith, documenting his concerns about the discounts and rebates that Celgene was offering for Otezla. FE 7 also told Smith that Celgene should never "pay to play," i.e., offer rebates and deep discounts in exchange for market access, as that would prevent Celgene from maximizing its profits. Notwithstanding FE 7's warnings, Celgene pressed ahead with its ill-fated "pay to play" plan for gaining market access.

102. FE 7 also stated that, critically, Otezla was far worse than Humira, Amgen's Enbrel (etanercept)—a biologic treatment manufactured by Amgen that has been available to treat PA since 2002 and psoriasis since 2004—and other competitors in terms of efficacy. The drug's inferiority to numerous established competitors in the marketplace made market penetration, and thus any attempt to increase revenues from Otezla sales, even more difficult.

103. FE 7 added that these impediments to growing Otezla net sales were exacerbated by the fact that, from the date of the Otezla launch, Smith hired extremely inexperienced sales representatives to sell the drug.

104. Echoing the accounts of FE 7, former Celgene sales representatives from every corner of the country all told the same story: for several fundamental reasons that remained unchanged throughout 2015, 2016 and 2017, the growth rate of Otezla sales was essentially flat.

- FE 8, a Celgene Sales Representative in the Northeast Region, confirmed that his annual Otezla sales were flat the entire time he worked for Celgene, from early 2014 through late 2017.

- FE 9, a Sales Territory Manager in the Southwest Region, recounted that by 2015, the growth of his Otezla sales had flattened and were flat from 2015 until he left Celgene in March 2017.

- FE 10, a Celgene Sales Representative in upstate New York, stated that, during his entire time with Celgene (from early 2015 until the end of 2016), it was "certainly a struggle to sell" Otezla, particularly on the rheumatology side—i.e., for patients suffering from PA. As FE 10 explained, "[o]nce the buzz [around Otezla] had dropped off by 2016, and once providers got a sense [Otezla] wasn't going to work that well," growing sales of Otezla "started to become a huge issue." Thus, FE 10 recalls that "the consensus was that the growth was not sustainable by 2016."

- FE 11, a District Sales Manager for the Northeast Region, stated that by 2016, his prescription sales had flattened for the entire year and there was a decline in annual growth (vs. 2016).

- FE 12, a Sales Representative in the Northeast Region, similarly noticed a slowing of Otezla prescription sales, particularly around October 2016.

- FE 13, a Regional Sales Manager, said that it was virtually impossible for Celgene to sell enough Otezla to meet its 2017 guidance. Specifically, FE 13 stated that the idea that Otezla could ever achieve 40% year-over-year growth in net product sales in 2017, let alone the 57% growth Defendants projected in January 2017, was absurd. FE 13 explained that he had seen no indication that would justify that kind of projection unless Celgene was expecting some huge shift in the managed care environment, and that it makes no logical sense to see those numbers domestically.

105. The Otezla sales representatives confirmed that Celgene's executives had access to information showing that the Company was unable to increase the growth rate of Otezla sales before and throughout the Relevant Period. FE 14 stated that Celgene management knew of Otezla's struggles because all of the sales results were available to management through a computer program called "Tableau." FE 12 explained that Tableau is a computer data tool that Celgene uses to compile and analyze sales data that Celgene receives from IMS, a company that collects pharmaceutical data. Before and during the Relevant Period, the data available through Tableau for Otezla included straight volume, volume growth, number of prescriptions by territory, number of prescriptions by provider, and number of prescriptions attributed to each salesperson. According to FE 12, anyone from the sales side at Celgene could log on to Tableau and view the Otezla sales data. The degree of access to the data increased as you went higher up in the Company.

106. The former sales representatives also confirmed FE 7's account, uniformly attributing their struggles to grow Otezla sales to three main issues: (i) Otezla's inferior efficacy compared to its competitors, including the fact that Otezla worked slower than other drugs and was only effective for certain indications; (ii) challenges with insurance coverage for Otezla, including step-edits and preauthorization requirements; and (iii) various other obstacles that made it difficult for patients to get Otezla or negatively impacted the ability of sales representatives to sell Otezla. These persistent and widespread impediments to growing Otezla

sales rendered Celgene's 2017 Otezla guidance unattainable and Defendants' representations reaffirming that guidance materially false and misleading.

(a) Celgene Internally Viewed Otezla's Competitors As More Effective, Faster-Acting, and Covering a Broader Range of Indications

107. As numerous FEs recounted, the first fundamental barrier to growing Otezla sales before and throughout the Relevant Period was the fact that Otezla was not as effective as the other PA and psoriasis drugs from which it was attempting to capture market share.

- FE 9 explained that Humira produced positive results more quickly than Otezla. In addition, Otezla was not as effective as Humira for individuals who only suffered from psoriasis.

- FE 8 stated that Otezla's main competitors, Humira and Enbrel were simply more effective products with broader indications than Otezla. Humira and Enbrel could be prescribed to patients with mild to severe symptoms and typically worked within two to three weeks, whereas Otezla was only approved for mild to moderate indications and required up to four months to produce noticeable results. FE 8 referred to Otezla as "training wheels" compared to Humira and Enbrel.

- FE 10 confirmed that Otezla was difficult to sell because it was not as effective as its competitors, stating, for example that PA patients who had the disease for some time often did not respond well to Otezla. FE 10 received consistent feedback from rheumatologists that Otezla did not work well to treat PA.

- FE 11 added that there was an increase in competitor products entering the market both before and during the Relevant Period, and in contrast to Otezla's efficacy rate of approximately 33%, these new biologic competitors had efficacy rates between 50% and 75%. As FE 11 explained, these statistics made it difficult to convince doctors and patients to switch to Otezla.

- FE 13 likewise confirmed that the efficacy of Otezla was nothing groundbreaking and not nearly as efficacious as some of the other competitors.

- FE 12 and FE 14 also indicated that there were issues with Otezla's efficacy and FE 12 specifically stated that Otezla worked slower than other competitor products and that these competitor products had more efficacy data. FE 12 further noted that there were significant deviations between patients in terms of Otezla's efficacy.

(b) Celgene Understood Internally That the Market Was Oversaturated with Entrenched Competitor Drugs

108. Celgene's attempt to capture market share and increase Otezla sales both before and during the Relevant Period was further stymied by the sheer number of competitors in the PA and psoriasis treatment market and the fact that many of these drugs had been on the market for years and were well-accepted by physicians.

- FE 9 explained that the market for PA and psoriasis medications was oversaturated with competitor treatments, including established drugs like Humira. Physicians had many choices and Otezla was not at the top of the list; other, better known treatments were.

- FE 8 stated Otezla had difficulty capturing market share from its main competitors, Enbrel and Humira, as they had been on the market since 2002 and 2005, respectively.

- FE 11 similarly recounted that Humira was the "big kid on the block" and was already entrenched in the Northeast Region.

- Echoing FE 11, FE 13 indicated that the growth of Otezla sales was limited by Humira's successful saturation of the market.

- FE 13 explained that while the Company wanted Otezla to be the first in-step therapy, in light of its safety profile, that was just a "pipe dream" because Methotrexate (another competitor) was so much cheaper and had been in use for so long that it just was never going to happen.

- According to FE 13, Otezla was always destined to be a niche product as compared to its previously launched competitors.

(c) Insurance Coverage for Otezla Was Limited and Patients Faced Step-Edits and Preauthorization Requirements

109. Celgene's efforts to drive down pricing, in part, to avoid insurance step-edits and preauthorization requests, were largely unsuccessful until 2017, when several large PBMs finally agreed to cover Otezla as an initial PA and psoriasis treatment. As such, insurance companies threw up roadblocks that constrained Otezla's ability to gain market share and increase sales from January 2015 through at least 2016.

- FE 9 reported issues with insurance companies, including that pre-authorization was routinely denied for Otezla and patients had to try other first-line drugs due to insurers' step-edit requirements. Insurance companies initially would not budge on coverage for Otezla.

- FE 14 stated that Otezla suffered from challenges with insurance coverage, including step-edits.

- FE 10 stated that insurance providers were unwilling for an initial period to reimburse patients for Otezla.

- FE 11 explained that several of the managed care groups in the Northeast Region had step-edits in place that required patients to use and reject Humira and Enbrel before they would approve Otezla, and the appeals process was cumbersome, so most doctors and plans opted to take the easier route by prescribing other drugs.

(d) Other Barriers to Growth

110. The growth of Otezla sales was also constricted by the fact that some patients experienced difficulties in trying to fill their Otezla prescriptions and the fact that Celgene lacked experienced sales personnel. FE 9 recounted that Otezla was considered a specialty drug, and had to be ordered from specialty pharmacies, unlike Humira and Enbrel, which were readily available in traditional pharmacies. This limit on access made it harder for patients to obtain Otezla even if their doctors prescribed it and insurance companies covered it. In addition, like FE 7, FE 14 also reported that Celgene's Otezla sales representatives were very inexperienced, which adversely impacted their ability to sell Otezla.

(e) Otezla Faced Barriers to Growth in the European Markets

111. Former Celgene employees involved with Celgene's efforts to expand Otezla into European markets similarly reported challenges to introducing Otezla into these markets and growing Otezla sales to meet the Company's unrealistic sales guidance.

112. FE 15, a senior member of the Pricing and Market Access group throughout 2015, was charged with creating pricing and market access models for reimbursement applications that

Celgene submitted to foreign national healthcare organizations in conjunction with efforts to obtain approval to market Otezla in Europe. As FE 15 explained, before and during the Relevant Period, there were two main hurdles before a drug could be marketed outside the U.S.: (i) the drug must be approved by the foreign counterpart to the FDA; and (ii) a reimbursement application must be accepted by the national healthcare organization charged with evaluating, among other things, the efficacy, cost and potential patient base for a drug.

113. In developing the models for Celgene's reimbursement applications, FE 15 struggled with Otezla's lack of compelling efficacy data because the models are usually driven by a drug's efficacy compared to other medications that are already in the market space. As he explained: "Otezla is worse than other things on the market so there was very little for me to work with." Because the data for "Otezla wasn't any better and was much worse than all of the competitors, it was very difficult to find the value" to support the reimbursement application models. FE 15 provided the Otezla models for the reimbursement applications to Zhang, Celgene's Global Head of HEOR, Pricing and Market Access, who in turn presented them to Defendant Smith.

114. Based on his review of the Otezla Phase II and Phase III trial data, FE 16, a high-ranking member of HEOR and Pricing for the U.K., stated that Otezla was inferior to its biologic competitors in terms of response rate and efficacy. It was his understanding that Otezla had a response rate that was 50% of the rate of biologics. Otezla's main advantage was that it was an oral medication, but the response rates for patients taking Otezla were "nowhere near" a biologic like Humira.

115. FE 16 confirmed that, in the U.K., Celgene's strategy was to discount Otezla to just below the price of its biologic competitors to stimulate sales and capture market share.

However, clinicians and patients were not swayed by the discount because the clinician would put the two drugs side by side, and the modest discount was not enough to make a difference with such an inferior efficacy. As FE 16 further explained, it was aggressive and foolish to assume that clinicians would use Otezla over biologics; clinicians just want to use the best product with the best data. As a result, FE 16 recounted that the Otezla sales and uptake forecasts compiled by Celgene for the U.K. and Ireland were overly aggressive. FE 16 added that his colleagues in other parts of Europe shared the same feeling that the Company's targeted sales figures were quite aggressive. FE 16 and his European counterparts at Celgene participated in discussions with independent advisory boards comprised of clinicians, local payers and various stakeholders. The advisory board members would consistently criticize Celgene, stating: "You're offering a biologic-like price without [] biologic-like efficacy."

116. According to FE 16, once approval was granted by the relevant U.K. regulatory body, the NICE, in late 2016, and Otezla was introduced into the U.K. marketplace, sales and uptake were "very slow and very low." FE 16 stated that they missed sales targets for five or six quarters and were continuing to struggle as late as the middle of 2018. The early sales targets were missed by close to 50%. FE 16 confirmed that both Celgene's European and U.S. leadership were well aware of the missed targets. Indeed, there was "business review meeting after business review meeting" concerning the missed targets, including, at one point in late 2016 or early 2017, a meeting in London between Defendant Smith and Business Unit Director Rob Moore.

3. Defendants Reaffirm the 2017 Guidance and Tout Otezla's Net Product Sales Prospects Throughout 2015 and Into 2016

117. Notwithstanding the numerous barriers that were impeding Otezla's net product sales and market share growth by January 2015, Defendants repeatedly represented that Otezla

was well accepted, that the data relating to Otezla sales was encouraging, and that For example, during the May 12, 2015 Bank of America Merrill Lynch Healthcare Conference, Smith lauded the purportedly "phenomenal" "acceptance of [Otezla]" for psoriasis and PA by new patients, claiming that Otezla was "off to a great start" and that Celgene was "very, very encouraged."

118. Defendants also presented nearly identical versions of the slide set forth below discussing "sustainable, high growth" and reassuring investors that the Company was "***on track*** to meet or exceed" its 2017 Otezla sales guidance at no fewer than five separate investor conferences, on March 4, May 12, June 10, September 17 and November 10, 2015:

119. At the May 11, 2016 Bank of America Merrill Lynch Healthcare Conference, Alles claimed that Otezla's "terrific launch" gave Celgene confidence in the Company's ability to hit the Otezla 2017 guidance. Alles went on to downplay certain impediments to growth such as the step-edits imposed by the insurance companies on new users of the drug, stating, "we understand the access environment very well, so some of those barriers that gave us all a little bit

of caution for the uptake of Otezla early have started to present themselves in ways where we can manage it, understand it, and in many cases, we have great advantaged positions now because of the profile of the drug."

4. Defendants Ignore Explicit Warnings from Celgene's Market Access Team that the 2017 Otezla Net Product Sales Projections Are Unachievable

120. Despite (i) Celgene's continuing struggles to grow Otezla net sales in light of insurance barriers and Otezla's inferior efficacy vis-à-vis its competitors, and (ii) management's receipt of explicit warnings regarding the Company's doomed "pay to play" strategy for gaining market access, Defendants maintained Celgene's aggressive 2017 sales guidance throughout 2016 and 2017. Furthermore, as discussed below, between July and December 2016, Defendants disregarded explicit warnings from high-ranking finance personnel within the Company who voiced grave, specific, and unequivocal concerns that the 2017 Otezla sales guidance was unachievable.

121. According to FE 17, a senior-level U.S. Market Access executive between early 2016 and late 2017, there was no Otezla revenue growth anywhere by 2016. FE 17 recalled that the lack of growth in Otezla sales and its fundamental causes were expressly communicated to the IIEC by no later than the third quarter of 2016. At this time, the IIEC was comprised of at least the following individuals: Defendant Smith; Defendant Curran; Tessarolo; Hunter Smith (Vice President, Finance); Tom Tomayko (Vice President, Commercial Development & Strategy, I&I); and Celgene's Head of Medical.

122. FE 17 and his team presented to the IIEC one to three times during each of the third and fourth quarters of 2016. Jim Kilgallon, Executive Director, U.S. Market Access, Pricing and Contracting, who worked with FE 17 and maintained much of the supporting Otezla payer and pricing statistics, presented with FE 17 at these meetings. During these presentations,

which focused on payers and pricing, FE 17 and his team expressly warned the IIEC that the 2017 Otezla guidance could not be met. FE 17 explained that the detailed research he reviewed and presented regarding payers and pricing showed that the forecasted Otezla sales for 2017 were not attainable. According to FE 17, Tessarolo also warned the IIEC in weekly meetings by the third quarter of 2016 that the 2017 Otezla guidance could not be met.

123. In the fourth quarter of 2016, FE 17 expressly advised the IIEC that the Otezla sales guidance should be lowered. FE 17 also specifically recalls that he and Kilgallon told Tessarolo directly that the guidance needed to be lowered. Tessarolo agreed and later confirmed to FE 17 that he, too, warned the IIEC that the guidance should be lowered, but the other members of the IIEC, which included Defendants Smith and Curran, insisted that the guidance would not be changed. Thus, FE 17 confirmed that by the third and fourth quarters of 2016 the IIEC was acutely aware that Celgene was not going to hit the repeatedly reaffirmed 2017 Otezla sales guidance numbers. According to FE 17, "***everyone knew that the actual stated forecast was not reasonable***" and could not be met.

124. FE 17 further recounted that the Forecasting team (which included Doug Bressette, Senior Director, Global Business Planning and Analysis for I&I) was "***told to change***" ***the numbers*** (i.e., the internal forecasts) by Smith and Curran to conceal the lack of growth.

125. FE 18, a direct report to Swartz, Celgene's Vice President of U.S. Market Access, confirmed that Smith and other Celgene executives were aware that Celgene was not going to meet its 2017 Otezla sales guidance by no later than the fourth quarter of 2016. FE 18 explained that Swartz made recommendations to the Corporate Pricing and Market Access Committee ("CPMAC"), the committee charged with monitoring and approving pricing and market access decisions, that the Company needed to reduce the 2017 guidance numbers, but she was ignored.

The CPMAC was chaired by Defendant Smith, and other members of Celgene's senior executive management would sit in as well.

126. When FE 18 first saw the 2017 Otezla sales guidance, his reaction was "***wow, there is no way in the world we were going to make [it] . . . it was crazy***." FE 18 described the guidance as a "moon shot." FE 18 indicated that the aggressive Otezla guidance did not even account for the introduction of new competition to the PA and psoriasis market—Defendants simply ignored this factor. FE 18 further explained that the guidance figures were based on the assumption that insurance reimbursement hurdles would be removed. To meet the Otezla sales numbers set by the CPMAC, Otezla would have had to completely transform the market space in less than twelve months, but this kind of transformation is unheard of unless a company introduces a curative drug. Otezla just did not have the efficacy or novelty to bring about the market change needed to meet the Company's sales guidance. FE 18 also confirmed that Otezla sales in the fourth quarter of 2016 were very flat and had been flat for quite some time before that.

127. The admonitions of Swartz, FE 18, and their colleagues responsible for pricing concerning the unachievability of Celgene's Otezla sales guidance were outright ignored by Defendant Smith, Defendant Curran and other members of Celgene's senior management. According to FE 17, Defendants refused to lower the guidance and instead put pressure on the salespeople to hit the impossible numbers.

128. Indeed, Defendants repeatedly reaffirmed the 2017 Otezla net product sales guidance to the market. For example, on April 27, 2017, Defendant Curran responded to an analyst question on a conference call claiming: "Importantly, if we look at the exit run rates out

of quarter 1 and into quarter 2, ***we do see the net sales rebounding and on track to deliver our 2017 guidance***."

129. According to FE 18, Swartz was fired in late 2017. FE 18 had reported to Swartz for a year and a half and never had any issues with her, stating that she was always very professional and was a great boss to work for. The consensus among FE 18 and his colleagues was that Swartz had been fired due to her consistent pushback regarding the unachievable Otezla sales guidance that Celgene repeatedly provided to the market. According to FE 18, Swartz was "scapegoated" and her termination was an attempt by Celgene to "pivot around her."

5. Defendants Marginally Lower the Upper Range of 2017 Guidance But Forecast Impossible 57%+ Growth in Otezla Sales

130. In January 2017, even after Defendants Smith and Curran were expressly advised by Swartz, Tessarolo, and others that Celgene's publicly-stated 2017 Otezla guidance could not be met, Defendants refused to revise the low end of the range and only modestly lowered the top end from $2 billion to $1.7 billion. Critically, Defendants also misleadingly projected 57% year-over-year growth in Otezla net product sales for 2017 compared to 2016. Specifically, on January 9, 2017, Celgene filed a Form 8-K with the SEC attaching a press release with the Company's 2016 preliminary results and its outlook for 2017. In this press release, Celgene stated that it expected Otezla net product sales of "approximately $1.5 [billion] to $1.7 [billion]" for 2017, representing 57% year-over-year growth.

131. Analysts reporting on Celgene's press release, including BTIG Equity Research, wrote that the "biggest driver" of the Company's overall 2017 guidance was Otezla, "which is expected to grow -58% YoY." SunTrust Robinson Humphrey wrote that even the narrowed Otezla guidance range "calls for significant growth." In addition, several analysts noted that Celgene's reaffirmation of the $1.5 billion low-end of the guidance range was in line with the

market's expectations. For example, RBC Capital Markets was focused on the low end of the range, writing on January 9, 2017 that the $1.5 billion figure was "already expected." Evercore ISI wrote in a January 9, 2017 report that "CELG took the top end of Otezla guidance down from $2B to $1.7B, and the midpoint of Otezla guidance now tracks with consensus 2017 estimates of $1.54B." Similarly, J.P. Morgan stated in a January 9, 2017 report discussing Celgene's updated 2017 guidance that the consensus guidance for Otezla was $1.53 billion.

132. Multiple former employees confirmed that Defendants' forecasted 57% year-over-year growth was both unrealistic and unachievable. FE 19, a senior executive in U.S. Field HEOR, recounted that based on what his Market Access group was seeing in their interactions with and analyses of large payers, there was no way that the projected 57% year-over-year Otezla sales growth for 2017 was attainable. According to FE 19, in late 2016, when Defendant Smith was assessing the 2017 Otezla market access and setting the targets, the market did not support anything close to 57% growth. FE 19 continued, "even if Market Access was able to obtain 100% coverage [from insurance companies], it was unrealistic to obtain the kind of growth in Otezla sales that Smith was forecasting for 2017."

133. As FE 19 explained, Otezla's competitors, including Humira and Remicade, were deeply entrenched in the market space, which made it increasingly difficult for the sales team to come anywhere close to Smith's projections. FE 19 stated that in light of physicians' reluctance to prescribe Otezla over well-established competitor drugs, reaching the sales projection was "not going to happen." FE 19 recalled having conversations with Swartz and Claudio Faria, Executive Director and Group Lead of U.S. HEOR, concerning the unrealistic sales projections given what Market Access was reporting to management. According to FE 19, there was no way Defendant Smith could have interpreted what his Market Access team was saying and translated

that into 57% sales growth for Otezla in 2017. In other words, Defendant Smith ignored the Market Access team's warnings.

134. FE 17 also detailed multiple impediments to Celgene meeting the Company's 2017 Otezla sales guidance, and achieving the publicly-stated 57% year-over-year growth. FE 17 attributed the overall lack of growth in Otezla sales observed throughout 2016 and into 2017 to three main factors: (i) managed care was "underwater" by April 2016; (ii) as early as April 2016, new Otezla prescriptions and patients were down; and (iii) Celgene allowed wholesalers to buy in above their demand in late 2016. With respect to managed care being "underwater," FE 17 explained that when Celgene enters into a new PBM contract that requires Celgene to issue rebates, the Company ends up paying rebates for all existing prescriptions, i.e., the rebates apply both to new prescriptions and existing prescriptions. By virtue of the massive rebates due on the existing prescriptions, the PBM contracts are deemed "underwater" and undermine sales revenues. As early as April 2016, the rebates due on existing Otezla prescriptions covered by these "underwater" contracts were "significant" and amounted to millions of dollars. FE 17 stated that Celgene management should have given a warning to investors in the fourth quarter of 2016 because the IIEC knew about the rebate issue and the impact that it was going to have on the Company's 2017 Otezla revenues. However, no warning was given.

135. Further compounding the adverse effect from the "underwater" managed care contracts in the first quarter of 2017, at the end of 2016, Celgene permitted wholesalers to buy Otezla at reduced prices in excess of their demand. As FE 17 explained, in anticipation of a planned 2017 price increase for Otezla, many wholesalers asked to purchase in December 2016 the quantities of Otezla they were slated to purchase in January 2017, in order to take advantage of the lower price. Celgene could have refused the requests and required the wholesalers to

comply with their contracts to purchase the goods in 2017, but they chose not to do so. This decision, which FE 17 stated was motivated by management's desire to make the fourth quarter 2016 Otezla numbers look great, had a negative impact on the revenues in the first quarter of 2017, and thus Celgene's ability to meet its 2017 Otezla sales guidance.

136. FE 7 likewise confirmed that achieving a 57% increase in Otezla net product sales was "***impossible***" given Celgene's "pay to play" strategy (*see supra* ¶ 101). FE 7, who identified multiple barriers to Otezla's ability to capture market share (*see supra* ¶¶ 97-103), added that "there isn't any way to grow [Otezla] revenue by 57%." FE 7 was very vocal to senior management (i.e., Alles, Smith, Curran) and specifically told them that he did not think Otezla's growth would continue because of the step-edit hurdles and the saturation of competitor drugs in the market. FE 7's warnings, however, were ignored.

137. Consistent with FE 7, FE 8 stated there was no way Celgene could meet the 57% year-over-year growth forecasted as part of the January 2017 Otezla guidance. FE 8 stated that Otezla sales continued to be flat into April 2017 and, as a result, he and his Regional Business Manager were "banging their heads against the wall."

138. The disappointing sales results and other issues rendering the 2017 Otezla guidance unachievable were again communicated to the IIEC in early 2017. However, Defendants again refused to heed the warnings. Specifically, FE 17 learned from Tessarolo that he had given a presentation to the IIEC in early 2017 concerning the disappointing Otezla sales and had warned the IIEC that the Company needed to downgrade its 2017 Otezla sales guidance. During this presentation, Defendant Smith cut off Tessarolo, stating that he had heard enough of the negative information.

6. Despite Continued Headwinds and Recognized Impediments, Defendants Reaffirm the Aggressive 2017 Guidance

139. On April 27, 2017, Defendants announced that Celgene's Otezla net product sales for the first quarter of 2017 fell short of the Company's expectations, with just a 14% year-over-year increase and a 1% sequential decline from the fourth quarter of 2016. Rather than disclose the true cause of the decline in sales, Celgene ***reaffirmed*** the forecasted 57% year-over-year growth for Otezla sales, stating that the "Updated 2017 Guidance" for Otezla was "Unchanged."

140. During the April 27, 2017 first quarter conference call, Kellogg represented that "sequential performance from Q4 to Q1 is always impacted by several items . . . Otezla is impacted by managed care dynamics that drive lower total marketplace prescriptions for psoriasis therapies in Q1." Kellogg also tried to excuse the poor first quarter results by citing to the "higher gross-to-net adjustment related to new contracts with several large payers that were implemented in January," reassuring investors that the new PBM contracts and elimination of step-edits would improve market access, and by extension, Otezla net product sales for 2017: "These new contracts approximately doubled the number of patient lives who can now access OTEZLA without being required to step through a biologic therapy, which has already improved OTEZLA's market share in these accounts." Smith further claimed that "[w]e initiated a number of activities that will expand the addressable population for OTEZLA worldwide, laying the groundwork for a highly successful year ahead," stating that "[w]e can see that early gains are already evident after only 1 quarter from this contracting strategy."

141. In truth, Defendants had no reasonable basis for representing that new PBM contracts and the removal of step-edits would improve Otezla sales and help the Company hit its 2017 guidance. As detailed below by multiple former employees, the removal of step-edits and the newly negotiated contracts with the insurance companies and PBMs did not offset Otezla's

struggling sales in light of the myriad other issues depressing the sales numbers and, thus, would not suffice to make up the yawning gap in sales.

(a) Removal of Step-Edits Was Not a Panacea for Otezla's Lackluster Sales

142. Defendants acknowledged internally that Celgene needed a corresponding increase in Otezla sales to counterbalance the increased expenses and lower margins associated with the new contracts to remove the step-edits imposed by the insurance companies. According to FE 12, after Celgene spent a lot of money for "payer wins" (i.e., the removal of step-edits and other requirements by insurance companies), there was a push from corporate and District Managers to increase the sales volume to offset the higher expenditures and lower margins. As discussed above, however, a laundry list of additional issues, including the lack of efficacy and increased competition, continued to negatively impact Otezla sales (*see supra* § IV.B.2) despite the increased removal of step-edits by insurance companies. As FE 9 confirmed, even if Celgene managed to remove the step-edits, it would not solve the sales issues for Otezla because, among other things, physicians had been working with competitor drugs for many years and it was easier for them to prescribe medications they were used to and knew worked well.

143. During meetings in November or December of 2016 with Defendant Curran, Tessarolo, Swartz, Grausso, Willcox, and Rob Owen ("Owen"), National Sales Director, FE 7 continued to warn these executives that paying to remove the step-edits for Otezla was not a cure for the drug's broad-based market access challenges.

144. FE 7 indicated that while Celgene did remove some step-edits for Otezla in 2017, Celgene's leadership had previously made decisions that hampered Otezla's market access and destroyed its "best price" beginning as early as the 2014 launch (*see supra* ¶¶ 98-101). In addition, not all payers agreed to remove step-edits, including United, Aetna, Cigna, and Blue

Cross Blue Shield. Furthermore, FE 7 stated that even if 10 million individuals obtained access to Otezla through the removal of step-edits, not all of them would actually buy Otezla. In short, the removal of the step-edits was too little too late, and could not spur on Otezla sales enough to close the widening gap between the actual Otezla sales and the Company's knowingly unreasonable 2017 guidance.

(b) Many of the New PBM Contracts Were "Downgraded" in 2017

145. Unbeknownst to investors, Defendants' April 27, 2017 representation that the newly-entered PBM contracts would help drive the Company's 2017 Otezla sales was undermined by the fact that many of the PBM contracts took several months to generate revenues and, as a result, the Company reduced the revenue expectations associated with these contracts.

146. Specifically, FE 18 stated that several of the new PBM contracts Celgene entered into in 2017 covered patients who were receiving their Otezla prescriptions for free or at a reduced cost through various forms of patient assistance and other initiatives, such that Celgene was earning only minimal revenues related to these patients' prescriptions. Even after the new PBM contracts became effective, these patients continued to receive their Otezla prescriptions at little to no cost until their prior entitlements expired, at which point they were brought under the new reimbursement scheme. FE 18 explained that it was not until this process was complete, which could take one or two years, that Celgene started to earn revenues on these prescriptions. In other words, just because new PBM contracts went into effect in 2017, Celgene did not see increased revenues from prescriptions for many covered patients until months later.

147. FE 18 said that his Market Access team worked closely with the pricing team to assess how the new PBM contracts were performing throughout 2017. FE 18 stated that it was clear from the beginning of 2017, based on the models that his team was running monthly, that

the PBM contracts were not meeting revenue expectations. FE 18 communicated the fact that the contracts were underperforming to his boss, Swartz, and he understood that she reported this information to the CPMAC. According to FE 18, Celgene did not lower expectations for the PBM contracts even when presented with data showing that the contracts were underperforming; by contrast, when his team presented data showing that some contracts were outperforming, Celgene quickly raised the revenue expectations for those contracts.

148. Celgene eventually internally lowered the expectations on many of these PBM contracts. FE 18 recalled seeing a bar graph that depicted the original expectations, the actual numbers, and a revised, lowered expectation. The original expectation was "through the roof." While the revised expectations were closer to the current performance, this was after they had been significantly lowered, by amounts that "took [him] aback." Rather than communicate this to investors, Defendants left the market with the false impression that the new PBM contracts would help drive Otezla's 2017 sales.

7. Defendants Slash Otezla and I&I Guidance, Blaming Market-Wide Effects

149. It was not until the end of the third quarter of 2017 that Celgene finally admitted to investors what Defendants had known for years: the 2017 Otezla guidance could not be achieved. On October 26, 2017, Celgene stunned the market by announcing that, in light of the dismal Otezla sales numbers, the Company had slashed the 2017 guidance by more than $250 million, providing updated guidance of $1.25 billion compared to the $1.5 billion to $1.7 billion range Defendants reaffirmed just weeks earlier. Defendants also revised the 2020 I&I guidance down from over $4 billion to between $2.6 billion and $2.8 billion due to the grim Otezla sales.

150. During the third quarter 2017 conference call that day, Defendants tried to blame the dramatic reduction of the Otezla guidance on slowing growth across the dermatology market

and other market-wide challenges. Curran cited the "market deceleration" and characterized the Otezla market as "increasingly dynamic and competitive." Alles claimed: "[O]ur 2017 forecast assumptions did not adequately anticipate the deep and persistent slowing growth of the psoriatic arthritis and psoriasis markets, especially during the entire third quarter. When combined with the discounts tied to the execution of our ongoing managed-care contracting strategy, we missed our third quarter OTEZLA sales target." Kellogg similarly attributed the reduction in the Otezla guidance to the "market-wide challenges in the U.S. dermatology market."

151. Former Celgene employees knowledgeable about the real reason for the slashed guidance reported that these explanations were not accurate. FE 18, for example, rejected Defendants' claims that the Otezla miss was due to a slowing of the psoriasis and PA markets, particularly during the third quarter of 2017, as well as increasing competition, calling this purported explanation "***bullshit***." FE 18 explained that there was no way that Celgene's leadership was unaware of the fact that there would be more products entering the market in 2017. In addition, FE 18 confirmed that the market did not change rapidly in the third quarter of 2017. As he explained: "***We saw what was happening way before then***. ***We had monthly meetings with the contract and pricing teams . . . very early on in 2017***." FE 18 stated that there was "worry" and "concern" at these meetings. As FE 18 further stated: "We were in trouble with our Otezla contracts. You heard that from a lot of the pricing and contract people." Thus, according to FE 18, there was no way that Celgene's leadership was unaware of the looming guidance miss long before the third quarter of 2017.

152. The accounts of the other former Celgene employees discussed above similarly confirm that the 2017 Otezla guidance was unattainable from January 2015, well before the start of the Relevant Period (*see supra* § IV.B.2).

153. Analysts reacted quickly and negatively to the Company's guidance reduction and expressed a lack of confidence in Celgene's ability to execute going forward. As J.P. Morgan wrote in an October 26, 2017 report:

> A week after a high-profile (albeit also high-risk) Phase 3 asset failed [GED-0301], the company reported a big miss for Otezla and a sizable cut to overall 2020 guidance. This is clearly not a recipe for success for an over-owned stock in a skittish market. The question now is what happens from here? . . . . Sentiment has taken a tremendous hit, management faces a major credibility issue (at least based on our investor conversations), and generalists may be running for the hills after this week that more closely resembled a Halloween horror film than a typical 3Q biotech earnings season.

154. Raymond James commented that "today's update substantially alters our outlook and confidence in the company's ability to execute":

> We previously viewed Celgene's immune & inflammatory (I&I) franchise as a key driver to facilitate a revenue diversification effort away from Revlimid. However, with GED-301 now eliminated, and Otezla appearing to stumble, revised FY20 targets indicate an increasing reliance on the hematology franchise (rather than decreasing), which is the opposite of what we'd hope to see over time. Even if ozanimod data shows differentiation, we think CELG has now become a "show me" story[.]

155. On the news of Celgene's steep guidance reduction, the price of the Company's common stock declined $19.57 per share, or more than 16%, on heavy trading volume from a close of $119.56 per share on October 25, 2017 to a close of $99.99 per share on October 26, 2017.

C. FOR OVER A YEAR, DEFENDANTS FRAUDULENTLY CONCEAL THE NEED TO COMPLETE ADDITIONAL TESTING THAT JEOPARDIZED THE OZANIMOD NDA

156. The third piece of Defendants' three-pronged plan to replace Celgene's revenue stream from Revlimid was Ozanimod. Ozanimod was initially developed by Receptos to treat

RMS and UC.[7] MS is the most common autoimmune disease of the central nervous system, affecting an estimated one million people in the U.S.

1. Celgene Acquires Receptos and Installs Celgene Personnel to Oversee the NDA Submission for Ozanimod

157. On July 14, 2015, Celgene agreed to purchase Receptos for $7.2 billion. In its press release announcing the acquisition, Celgene trumpeted that "[t]he transaction adds Ozanimod" which, based on clinical studies, "demonstrated several areas of potential advantage over existing oral therapies for the treatment of [UC] and [RMS] . . . ." Celgene projected potential annual Ozanimod sales of up to ***$6 billion***, and analysts commenting on the Receptos acquisition zeroed in on the drug's anticipated power to generate revenue. As one commentator later remarked, Ozanimod was "the crown jewel in Celgene's $7.2 billion acquisition of Receptos, Inc." In light of the Receptos acquisition, Celgene revised its 2020 revenue guidance for the I&I franchise up from $3 billion to over $4 billion.

158. Immediately upon acquiring Receptos, Celgene installed its own personnel at Receptos' headquarters in San Diego. As FE 20, a former senior executive in Clinical Development at Receptos, explained, after the acquisition, Celgene moved in and took over Receptos: "They [Celgene] were in charge. Receptos was not." FE 20 stated that Receptos was brought under the control of Celgene's New Jersey headquarters. From that point forward, Receptos was out of the decision-making loop and important decisions were made by Celgene in New Jersey or by on-site Celgene personnel. FE 21 stated that after the acquisition, Receptos' leadership was not allowed to make any decisions that had the potential to impact Celgene's

[7] MS disrupts the normal functioning of the brain, optic nerves, and spinal cord through inflammation and tissue loss, causing communication problems between the patient's brain and the rest of the body. Most people with MS have RMS, which is characterized by a relapsing-remitting disease course, whereby a patient's symptoms may remit for a period of time but then relapse.

stock price, and there were constant discussions between senior Receptos personnel and their counterparts and superiors at Celgene.

159. According to FE 20, Defendant Martin came from Celgene to Receptos to oversee the Ozanimod NDA filing. Martin formerly served as the Vice President, Head of Project Leadership, for Celgene's I&I franchise. FE 2, who worked in Clinical Research & Development in the Company's I&I franchise, described Martin as a "control freak" and Smith's right hand man, and confirmed that Martin was sent to San Diego as Managing Director for Receptos in late 2015 or early 2016. FE 2 recounted that Martin operated as the *de facto* chief executive at Receptos. (FE 2 also recalled that the Vice President of Clinical Research & Development reported to Defendant Smith.) FE 5, a former Director at Receptos, likewise described Martin as the CEO of Receptos after the acquisition, adding that Martin was in charge of the entire Receptos organization and reported directly to Smith.

160. FE 5 explained that once he was in power, Martin pushed out Receptos' previous upper management and replaced them with his friends from Celgene in New Jersey. Martin's best friend, Saillot, was brought in to serve as Vice President of Project Leadership, Regulatory Affairs, and Clinical Pharmacology at Receptos. FE 5 also recounted that Gary Cline, Head of Strategic Research and Innovation at Celgene, was another individual sent by Smith to San Diego to keep tabs on Ozanimod for Smith. FE 22, a Project Manager on the Ozanimod UC/CD team, corroborated that Martin reported directly to Smith and further confirmed that Saillot was Martin's second in command.

2. Celgene Touts Ozanimod's Advantages Over Gilenya

161. When Celgene acquired Receptos in 2015, the Company knew that if Ozanimod received FDA approval, its main competitor would be Gilenya (fingolimod), a drug manufactured by Novartis for the treatment of RMS. The Company therefore immediately

embarked on an aggressive campaign to hype the purported advantages of Ozanimod over Gilenya and to rush Ozanimod through the FDA approval process.

162. Gilenya has a mechanism of action that is similar to Ozanimod. Celgene, however, claimed that Ozanimod had the advantage of a much shorter half-life than Gilenya. Gilenya has a long half-life of 168 hours, or seven days; that is, half of the drug remains in a patient's body for seven days after it is taken. By contrast, Celgene claimed that Ozanimod had a much shorter half-life of just nineteen hours.

163. As one scientific paper from 2015 explained: "Having a shorter half-life and rapid peripheral lymphocyte recovery may provide [Ozanimod] with ***significant advantages***, including flexibility in treatment with other immune-modulating agents as needed or allowing for a rapid switch to alternative therapies if the patients [sic] disease flares while on therapy."

164. Immediately after acquiring Receptos, Celgene began touting the supposed advantages of Ozanimod over Gilenya and other oral RMS medications, including the drug's purportedly shorter half-life. For example, during the Robert W. Baird & Company, Inc. Healthcare Conference on September 9, 2015, Defendant Smith pointed to the "different half-life . . . that you see with the S1P1 with Ozanimod, that you don't see with Gilenya," noting that this "could potentially be some reason to differentiate."

165. Armed with this supposed competitive advantage, Celgene sought to capture Gilenya market share following FDA approval of the Ozanimod NDA, which was expected in 2018. In a landscape-altering ruling, however, in October 2015, the U.S. Patent and Trademark Office ("PTO") quashed Novartis's Gilenya patent claims in response to a challenge by generic competitors, paving the way for the entry of fingolimod generics into the RMS market by the end of 2019. As one publication characterized the PTO's decision and its impact on companies like

Celgene: "***[I]t's not good for rival pharma companies, either***. They'll also have to contend with copycat versions of Gilenya, the first oral treatment for MS."

166. Thus, despite Ozanimod's purportedly superior half-life and safety profile, the availability of cheaper generic alternatives with a similar efficacy starting in 2019 would make it more difficult for Ozanimod to gain widespread acceptance among RMS patients. As a result, Celgene was highly motivated to file its Ozanimod NDA and seek FDA approval before the end of 2017, in hopes of establishing market share before the wave of generic fingolimod competitors hit the market in 2019.

3. Celgene Disregards FDA Guidance and Industry Practice and Fails to Undertake Critical Testing for Ozanimod Metabolites

167. In announcing the Receptos acquisition, Celgene represented that it anticipated no obstacles to FDA approval. For example, the Company told investors on July 14, 2015 that the data from the two ongoing Phase III clinical trials, the RADIANCE and SUNBEAM RMS studies, "are expected in the first half of 2017 to support a RMS approval in 2018." Defendants continued to make identical representations throughout the Relevant Period. However, unbeknownst to investors, after Celgene discovered the Metabolite in November 2016, it failed to conduct and report critical testing required to receive FDA approval of Ozanimod in early 2018, thus dooming the drug's prospects for this rapid approval timeline.

(a) FDA Guidance and Industry Practice Standards on Metabolite Safety Testing

168. Pursuant to FDA guidance, in order to avoid significant delay in the review and approval of a new drug application, drug companies are directed to identify all metabolites early on in the drug development process and to conduct extensive safety testing of any active metabolites that are discovered during the course of these pharmacological analyses. When a drug is administered to a patient, the drug can be metabolized (i.e., chemically altered) by the

patient's body, resulting in the formation of one or more metabolites. Metabolites are characterized as either "active" or "inactive." Active metabolites continue to produce effects in the body after their formation, whereas inactive metabolites do not. Active metabolites can accumulate in the body following multiple doses of a drug and may ultimately alter both the safety and the therapeutic effects of the drug. Thus, according to a seminal article on the subject, understanding "the metabolic fate of a drug candidate in preclinical species and humans is a ***key factor*** in new drug development, registration and ultimate use."[8]

169. The importance of metabolite identification and testing has long been recognized. Since 1985, federal regulations have ***required*** that NDAs include "[a] section describing the human pharmacokinetic data" (i.e., information about how a drug moves through the body), including "[a] summarizing discussion and analysis of the pharmacokinetics and the metabolism of the active ingredients . . . of the drug product."

170. In 2002, Dr. Thomas A. Baillie (Professor of Medicinal Chemistry and Dean *Emeritus* for the University of Washington School of Pharmacy, and former Vice President and Global Head of Drug Metabolism and Pharmacokinetics at Merck & Co.), et al. authored a paper entitled "Drug Metabolites in Safety Testing" that summarized the deliberations of a multidisciplinary committee regarding the critical importance of identifying and testing metabolites as early as possible in the drug development process.[9] In this paper, often referred to as the "MIST" paper, Baillie and his co-authors recognize "the increased attention being paid by

[8] Human Radiolabeled Mass Balance Studies: Objectives, Utilities and Limitations, Natalia Penner, Lewis J. Klunk and Chandra Prakash, May 2009. At the time of this paper, Penner, Klunk and Prakash were employed in the Department of Drug Metabolism and Pharmacokinetics at Biogen, a pharmaceutical company focused on discovering, developing, and delivering therapies for people affected by serious neurological and neurodegenerative diseases.

[9] Drug Metabolites in Safety Testing, Toxicology and Applied Pharmacology 182, 188-196 (2002).

both pharmaceutical companies and regulatory agencies to the role of metabolites as potential mediators of the toxicity of new drug products."

171. Baillie, et al. highlight the fact that the early identification of metabolites in drugs at the development stage is critical to evaluation of the drug's safety. The MIST paper also stated that "it seems reasonable to expect that the sponsor would wish to develop an understanding of the metabolic fate of the drug candidate in humans ***prior*** to the initiation of large Phase III clinical trials." Baillie, et al. further stress that "the importance of the animal and human ADME [Absorption, Distribution, Metabolism and Excretion] studies [used to identify metabolites] ***cannot be overemphasized***, the results of which need to be viewed in the context of all available pharmacology and toxicology data."

172. Relying on Baillie's 2002 MIST paper, the FDA published industry guidance for the Safety Testing of Drug Metabolites in 2008 and reaffirmed this guidance in November 2016. The FDA's guidance calls for "the identification of differences in drug metabolism between animals used in nonclinical safety assessments and humans ***as early as possible*** during the drug development process." The FDA warns that "[t]he discovery of disproportionate drug metabolites late in drug development can potentially ***cause development and marketing delays***." Thus, the FDA "encourage[s] contacting the FDA early in drug development to discuss these issues."

173. As Baillie subsequently explained in a 2009 paper, the FDA's metabolite testing guidance "underscores the need for sponsors to conduct studies on the metabolic fate of drug

candidates ***at an early stage of clinical development, such that issues of disproportionate human metabolites may be addressed prior to the initiation of large-scale clinical trials***."[10]

174. Testing for the presence of metabolites in humans is conducted through so-called radiolabeled mass balance studies, wherein a radioactive "label" (typically Carbon-14) is added to the drug to allow for the tracking of metabolites in the blood, plasma, urine, and feces collected from patients. As Penner, *et al.* explain, radiolabeled mass balance studies are "viewed as the primary source of data on human metabolites from which a decision can be made regarding the need for further safety assessment in preclinical species," stating that "[h]uman radiolabeled mass balance . . . studies are ***required*** by regulatory authorities for the registration of a new drug, and therefore, are an integral part of the majority of drug development programs." Baillie also acknowledges the importance of mass balance studies utilizing a "radiolabeled drug" in identifying metabolites, stating that these studies are "***generally [ ] accepted as the 'gold standard' method for defining the fate of a drug candidate in man***."

175. Following the identification of metabolites through appropriate studies, certain metabolites require additional testing. As the FDA explains, "when the metabolic profile in humans is similar to that in at least one of the animal species used in nonclinical studies," standard animal toxicology studies are generally deemed sufficient for FDA submission. In other words, if the metabolite is present in similar amounts in humans as in the animals used for toxicology studies, those animal toxicology studies can "stand in" for human toxicology studies. However, as the FDA guidance recognizes, there are cases when "the metabolite is formed only in humans and is absent in the animal test species or [ ] the metabolite is present at

[10] Approaches to the Assessment of Stable Chemically Reactive Drug Metabolites in Early Clinical Trials, Chem. Res. Toxicol. 2009, 263-266.

disproportionately higher levels in humans than in the animal species." In these cases where such an imbalance exists between the metabolite's presence in humans as compared to animals, the drugmaker should conduct additional testing of the metabolite ***before*** filing the NDA for the drug. In describing the type of metabolites subject to additional studies, the FDA guidance provides:

> Generally, metabolites identified only in human plasma or metabolites present at disproportionately higher levels in humans than in any of the animal test species should be considered for safety assessment.

The FDA guidance further provides that human metabolites can raise a ***safety concern*** when they "form[] at greater than 10 percent of parent drug systemic exposure at steady state."

176. Baillie likewise stresses the importance of determining whether any of a drug's metabolites are present at higher levels in humans than in animal test species. Baillie states that if an imbalance is detected, the next step is to determine whether "such 'disproportionate' human metabolites exceed 10% of the area under the plasma concentration vs time curve (AUC) of the unchanged parent"—a further red flag. The AUC, or "Area Under the Curve," percentage is significant as it reflects the actual body exposure to a drug after administration of a dose of the drug.

177. If a disproportionate metabolite is identified, the FDA guidance sets forth multiple categories of studies "to be conducted to assess the safety" of such a metabolite. This battery of tests includes: general toxicity studies, genotoxicity studies, embryo-fetal development toxicity studies, and carcinogenicity studies.

178. Penner, et al. recognize the need for further tests regarding disproportionate metabolite levels identified during drug development and, thus, the importance of early metabolite identification: "Additional toxicological testing on metabolites that display higher exposure in humans than preclinical animal species may be required. ***For such metabolites, the***

[FDA] Guidance recommends that they be synthesized and evaluated by direct administration to test animals and the study reports be submitted prior to commencement of large-scale clinical trials."

(b) Celgene Fails to Conduct Critical Metabolite Testing in Contravention of Governing Guidance and Industry Standards

179. Notwithstanding the need for additional, time consuming safety studies with respect to any disproportionate metabolites that are identified, Celgene pushed forward with large-scale Phase III clinical (i.e., human) trials of Ozanimod after the Receptos acquisition in an effort to expedite submission of the Ozanimod NDA. In doing so, the Company delayed administration of the "gold standard" radiolabeled mass balance study.

180. After the Receptos acquisition, Celgene forged ahead with the Phase III SUNBEAM and RADIANCE trials and only later circled back to finish the necessary Phase I testing. As FE 21 explained, Celgene reported to the market the "sexier" efficacy findings for Ozanimod first, and then sought to backfill the results from the "non-sexy" clinical pharmacology testing that must be conducted throughout drug trials. These "non-sexy" tests examine aspects such as how a drug impacts the body or absorption rates and are typically completed during Phase I (i.e., the first in-human studies). With respect to Ozanimod, however, FE 21 reported that Celgene was still undertaking many Phase I Ozanimod studies in 2016, notwithstanding that the Company had been proceeding with large-scale Phase III clinical trials for more than a year.

181. The Code of Federal Regulations ("CFR")—a codification of the rules established by U.S. Federal Government agencies, including the FDA—confirms that Celgene's decision to push forward with the Phase III trials without first completing the threshold Phase I studies was out of sequence. As these regulations explain, "the clinical investigation of a previously untested

drug is generally divided into three phases," Phase I, II and III, and "***in general the phases are conducted sequentially***." 21 C.F.R. § 321.21. Phase I studies "are designed to determine the metabolism and pharmacologic actions of the drug in humans," among other things. Phase III studies, by contrast, "are performed after preliminary evidence suggesting effectiveness of the drug has been obtained."

182. Celgene's acceleration of the Ozanimod Phase III testing—despite not having completed Phase I testing, including the "gold standard" radiolabeled mass balance study—conditioned the market that the Company was in position to file the Ozanimod NDA by the end of 2017. For example, Celgene represented in a November 5, 2015 slide presentation given during the Company's third quarter conference call that "Ozanimod Clinical Development Continues to Progress on or Ahead of Schedule." Unaware that Celgene had not yet completed Phase I testing, analysts reporting on the conference call repeated Defendants' representations regarding the timing of the NDA for Ozanimod. Jefferies Group LLC listed the "potential launch in MS" for Ozanimod as mid-2018. Morningstar similarly reported that Ozanimod is "poised to reach the market in 2018" and also referenced Ozanimod's "potential approval in multiple sclerosis" in 2018. An RBC Capital Markets analyst also wrote that Ozanimod was "ahead in timing."

4. Celgene Belatedly Identifies a New Metabolite that Imperils the Company's Timeline for FDA Approval

183. Celgene did not undertake the testing necessary to identify all of Ozanimod's metabolites until October 2016—fifteen months after first acquiring Receptos. On October 17, 2016, Celgene began recruiting study subjects for a "**Phase I**, Single-Centre, Single Dose Oral Excretion Balance Study of [14C]-RPC1063 in Healthy Male Adults" (the "Mass Balance Study"). One of the stated primary objectives of this study was "[t]o determine how the drug

[Ozanimod] moves through the body [i.e., is metabolized] and how fast it is removed from the body." Through this Mass Balance Study, which was completed on November 21, 2016, Celgene identified the Metabolite—a disproportionate and highly active metabolite, later labelled as CC-112273—which triggered the need for the additional testing described in the FDA guidance.

184. Celgene's laggard discovery of the Metabolite is confirmed by former Celgene employees. For example, FE 20 stated that the Metabolite was discovered in 2016 during a radiolabel drug study. FE 21 similarly stated that the Company identified a new metabolite approximately a year before the Company submitted the Ozanimod NDA in December 2017.

185. FE 21, who had first-hand knowledge of the discovery of the Metabolite, discussed the Metabolite with his manager and stated that its discovery was of great concern. As FE 21 explained, his manager told him not to tell anyone about the Metabolite finding; instead, FE 21's manager and the leader of Receptos, who other former employees have identified as Defendant Martin, would tell him who needed to know. FE 21 understood that the individual with his parallel role at Celgene and his manager's equivalent at Celgene both knew about the discovery of the Metabolite. FE 21 also learned that members of Celgene's senior leadership knew about the discovery of the Metabolite and received updates on the issue.

186. Upon discovering the Metabolite in November 2016, Defendants recognized that they had to conduct additional studies of the Metabolite prior to submitting the Ozanimod NDA. The results of the Mass Balance Study revealed that the concentration of the Metabolite in humans, measured by the AUC, far exceeded the 10% threshold trigger for additional testing set forth in the FDA guidance. Moreover, as the Company would later disclose after the Relevant

Period (*see infra* ¶ 224), the Metabolite is disproportionately formed in humans and accounts for 90% of Ozanimod's activity.

187. Thus, Defendants knew in November 2016 that the Metabolite triggered ***both*** of the FDA-established thresholds for additional testing. In other words, because the Metabolite was: (i) "present at disproportionately higher levels in humans than in any of the animal test species"; and (ii) "formed at greater than 10 percent of parent drug systemic exposure at steady state," it "raised a safety concern" and should have been "considered for safety assessment."

188. In addition, the Mass Balance Study revealed that the half-life for the Metabolite was significantly longer than Ozanimod's half-life of nineteen hours, which the Company had repeatedly promoted as a competitive advantage for Ozanimod over Gilenya during the Relevant Period. In fact, the Company waited until after the Relevant Period to disclose that the half-life of the Metabolite was ***ten to thirteen days***.

189. Multiple witnesses confirm that Defendants knew that Celgene needed to conduct further testing on the Metabolite prior to filing the Ozanimod NDA. FE 21 recounted that immediately after discovering the Metabolite, he and others at Celgene began working on several additional studies. FE 21 characterized these efforts as "herculean" and "monumental," explaining that Celgene started new studies and went back and looked at closed findings to extract more data. FE 21 also indicated that Celgene's senior leadership was briefed on the discovery of the Metabolite and the ongoing characterization efforts "quite some time before the filing" of the NDA. Furthermore, FE 21 confirmed that, over time, the team working on issues surrounding the Metabolite grew.

190. Similarly, FE 5 recalled that Tran, Receptos' Head of Clinical Pharmacology, confirmed the need for additional testing and studies of the newly discovered Metabolite during

an Ozanimod meeting in March or April of 2017. This meeting was attended by Martin, Saillot (who reported to Martin), Paul Frohna ("Frohna") (Vice President of Clinical Development and Translational Medicine, Receptos, who reported to Martin), Kopicko (Executive Director of Biometrics, Receptos, who reported to Martin), Darryl Penenberg ("Penenberg") (Director, Receptos, who reported to Kopicko), Aranda (Vice President of Clinical Development, Receptos, who reported to Martin), Brett Skolnick ("Skolnick") (Executive Director of Clinical Development, Receptos, who reported to Aranda), and others.

191. FE 5 stated that, at this meeting, Tran, who worked on the radiolabeled Mass Balance Study and was responsible for analyzing the Metabolite and preparing the pharmacokinetic report, discussed the high amounts of the Metabolite that were found in humans (but not in animals) and the need to conduct further studies. According to 5, Tran directed his comments to Martin and Saillot, and Martin and Saillot quickly shut down the conversation regarding the Metabolite and moved on to a separate testing discussion.

192. Despite discovering the Metabolite and the need to complete additional testing before submitting the Ozanimod NDA to the FDA—circumstances which jeopardized Celgene's timeline for NDA submission at the end of 2017—Defendants concealed and misrepresented these material facts from investors. For example, after discovering the Metabolite and recognizing the need for additional Phase I testing, Defendants deceptively represented to investors in Celgene's Annual Report on February 10, 2017 and in its quarterly report on April 27, 2017, that the status of Ozanimod's development was "Phase III," when in fact, substantial Phase I studies on the Metabolite were now required.

193. Defendants also continued to represent that Celgene was on track to submit the NDA before the end of 2017 and was only waiting on the final results from the Phase III

RADIANCE and SUNBEAM trials. Alles stated during the J.P. Morgan Healthcare Conference on January 9, 2017: "We have two Phase 3 trials that have completely accrued and expect to have the data during the first half of this year . . . ***contingent on that, we will file an NDA for Ozanimod in multiple sclerosis by the end of the year***." Alles said nothing about the discovery of the Metabolite two months earlier, the need for further testing as a result, or the impact this further testing would have on the end-of-2017 target for submission of the NDA. In reporting on the conference, J.P. Morgan analysts wrote that "NDA submission by Y[ear] E[nd] [20]17" was a "Key 2017 catalyst[]." A JMP Securities analyst similarly stated that "the submission of an NDA for ozanimod in patients with multiple sclerosis" was a "key 2017 corporate milestone[]."

194. The failure of GED-0301 increased pressure on Defendants to tout Ozanimod as a major revenue driver in light of the looming Revlimid patent cliff. During a two day meeting in March or April 2017, FE 5 recalled that at least one session focused on how Ozanimod needed to become a first line therapy for ***CD***, which was significant and unusual, given that GED-0301 was publicly represented to be Celgene's CD treatment, poised for FDA approval in 2019. FE 5 further stated that it would be strange for Celgene to have two drugs in development for the same indication. Moreover, FE 5 described how in meetings at this time, Defendant Martin, Kopicko, and Jean Louis Saillot ("Saillot"), Vice President of Project Leadership, Regulatory Affairs, and Clinical Pharmacology at Receptos, were pushing the Ozanimod CD team to show better efficacy for CD than GED-0301. FE 5 stated it felt "frantic" like "they were digging" to produce better results with Ozanimod.

195. FE 5 also recounted that Kopicko, in particular, was very concerned about the efficacy of GED-0301, and that Kopicko's team was trying to obtain better evidence of CD efficacy for Ozanimod than GED-0301 had produced. As an example, FE 5 cited SES-CD as a

metric on which Kopicko's team sought to show better results when treated with Ozanimod compared to GED-0301.

196. To accomplish this, Kopicko and others directed FE 5 to manipulate the Ozanimod Phase II CD testing protocol to achieve the desired result. At the Ozanimod Phase II CD team meetings in March or April 2017, which FE 5 regularly attended, FE 5 recalled Martin and Kopicko asking FE 5's team to widen certain testing parameters "to such a degree to make efficacy look better" in the Phase II Ozanimod CD testing. FE 5 stated that Kopicko ended up changing the testing, per Martin's request, in order to improve the apparent efficacy results for Ozanimod.

197. In addition, FE 5 stated that Martin and Kopicko directed Pharmaceutical Product Development, a third-party vendor who performed much of the statistical analysis on Ozanimod's CD efficacy, to assist in making Ozanimod appear more efficacious than it actually was. According to FE 5, these "frantic" efforts to produce positive results in the Ozanimod CD clinical trial were reflective of Celgene's undisclosed concerns regarding the efficacy of GED-0301.

198. Indeed, after Celgene received the results from the SUNBEAM and RADIANCE trials in the spring of 2017, Defendants repeatedly touted the findings of these Phase III studies and assured investors that, based on these results, Celgene planned to submit the Ozanimod NDA by the end of 2017. For example, on July 27, 2017, during Celgene's second quarter 2017 conference call, Defendant Curran stated: "We announced positive results from RADIANCE, our second Phase III trial of ozanimod in MS and are on track to file the U.S. NDA by the year end." Defendant Smith added, "we feel very, very good about the data that's emerging for ozanimod," never once mentioning the Metabolite.

199. These statements were materially false and misleading because Defendants touted the completion of the Phase III studies, putting the issue of Ozanimod's development status into play, but did not disclose anything about the discovery of the Metabolite or the need to complete additional, protracted, and laborious Phase I testing which undermined Celgene's promise to submit the NDA by year-end. As far as the investing public knew, Ozanimod was well beyond Phase I. Nothing was further from the truth.

200. Further deceiving investors, on August 7, 2017, the *Journal of Clinical Pharmacology in Drug Development* published a paper sponsored by Celgene and attributed to Tran and several other Celgene employees entitled "Cardiac Safety of Ozanimod, a Novel Sphingosine-1-Phosphate Receptor Modulator: Results of a Thorough QT/QTc Study." This paper stated that "Metabolism studies in animals identified 3 pharmacologically active metabolites (RP101988, RP101075, and RP101442) that have similar S1P selectivity and potency in vitro to ozanimod" and described the characteristics of these three metabolites. The article also included a Figure 1 that purported to identify the "Chemical structures of ozanimod ***and its active metabolites***."

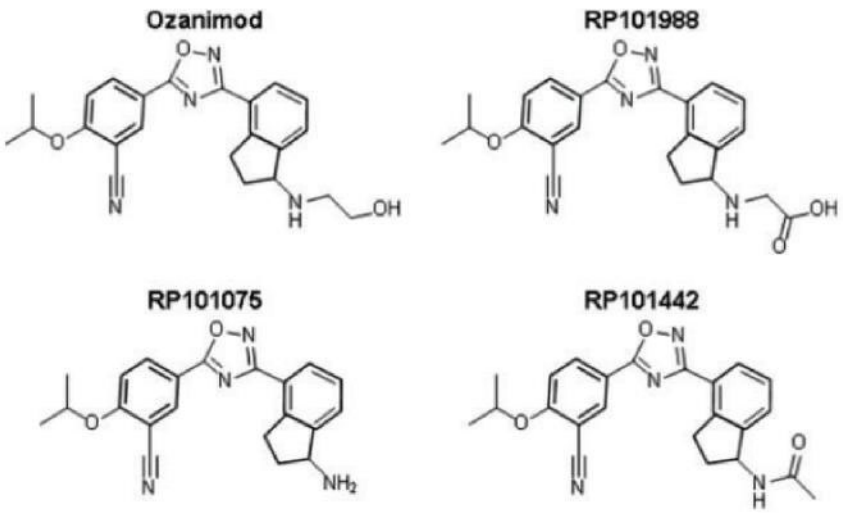


Figure 1

Chemical structures of ozanimod and its active metabolites.

201. Tran's paper made no mention of the Metabolite or the requisite additional testing, thereby misleading the scientific and investor community and perpetuating Defendants' concealment of the impact of the Metabolite on the Company's submission of the Ozanimod NDA.

5. Celgene Knowingly Submits a Facially Deficient and Incomplete NDA

202. As discussed above, Celgene was eager to rush Ozanimod to market so that it could compete directly with Gilenya and capture market share before Gilenya went off patent in 2019. Accordingly, Celgene determined not to wait until the additional Metabolite testing was complete and instead forged ahead with the NDA submission, knowing that it was deficient and almost certain to be rejected by the FDA.

203. FE 21 stated that he and his colleagues disagreed with the Company's decision to push forward with the NDA, instead believing that the Company should wait and finish all of the necessary testing and other work before submitting the NDA. He explained that he and his

colleagues could not understand why the Company would not invest the additional time to perform the necessary testing prior to submitting the NDA, especially when an RTF letter, which results from a deficient NDA filing, could severely damage Celgene's reputation. According to FE 21, there was no empirical reason for pushing ahead with the deficient filing. When FE 21 shared his thoughts with his managers, he was told to keep his views to himself.

204. In or around August 2017, FE 21 discussed with his colleagues the likely outcome of the Company's decision to file the NDA without the full results of the additional Metabolite testing. Specifically, FE 21 and his colleagues concluded that Celgene would receive an RTF letter due to the absence of the requisite test results. As FE 21 explained, ***the working team in "clinpharm" advocated that if Celgene submitted the NDA, it would get a refusal to file, and he thought other teams felt that way too from speaking with them***. FE 21 shared his concerns with his direct management. FE 21 and his colleagues also discussed the likelihood that the Company would blame Receptos personnel and the clinical pharmacology team for the RTF, and there would be massive layoffs as part of the fallout. As FE 21 stated, he and his colleagues were concerned that an RTF would cause "heads to roll locally and up top at Celgene."

205. In spite of these grim misgivings inside the Company, Defendants continued to paint a very different picture for the investing public. Confirming FE 5's account that Defendants had pivoted to Ozanimod as a potential treatment for CD after it became clear that GED-0301 did not work, on October 16, 2017, just three days prior to Celgene's announcement of the termination of the Phase III GED-0301 trial, Defendants issued a press release touting the results of the Company's Phase II studies of Ozanimod for treatment of CD and UC. The press

release stated that Ozanimod "demonstrated meaningful clinical and endoscopic improvements in patients with moderately to severely active Crohn's disease."[11]

206. Then, on October 26, 2017, Celgene held its third quarter 2017 conference call during which Defendants painted a very different picture for the investing public. During the call, Defendant Curran reiterated the false mantra that Ozanimod "remains ***on track for regulatory submission***, beginning with the U.S. by year-end . . . ." Defendant Smith presented a slide listing "Ozanimod FDA filing in RMS by YE:17" as an "inflection point[]."

207. According to FE 22, in November 2017, the FDA confirmed that Celgene was required to submit the results of the additional Metabolite testing with its NDA. Specifically, prior to filing the NDA, Celgene was involved in discussions with the FDA concerning the submission, which culminated in a November 2017 in-person meeting, known as a pre-NDA meeting. FE 21 understood that the "mini-NDA" package Celgene provided to the FDA in advance of the pre-NDA meeting and months before the NDA filing included information regarding the Metabolite and Celgene's work and findings to date.

208. FE 22 later learned that, during the pre-NDA meeting in November 2017, the FDA expressly told the Company that: (i) the FDA required the study results for the Metabolite; (ii) the results were very important; and (iii) the results had to be included in the Ozanimod NDA.

[11] Endoscopy is a nonsurgical procedure used to examine a person's digestive tract. Practitioners who study CD utilize a variety of scoring systems to assess and describe the severity of CD as well as measure its remission, including Simple Endoscopic Score for CD ("SES-CD"). Such endoscopic scores are also used by clinical trials to assessthe efficacy of various treatment agents on inducing and maintaining mucosal healing, and are considered "the gold standard tool indicating the presence or absence of active bowel inflammation." *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4898086/.

209. Even after the FDA explicitly told Celgene during the Company's pre-NDA meeting that Celgene must include the results of the additional Metabolite studies as part of its NDA submission—thus confirming what the Company had already recognized internally for months—Celgene pressed ahead with its plan to file the NDA without the test results, knowing that it was almost certain that the FDA would reject the NDA.

210. FE 22 confirmed that the Company moved forward and submitted the Ozanimod NDA without the required data in December 2017. FE 22 explained that one of the additional Metabolite studies was underway in December 2017, but results of that study were not to be received until April 2018—four months after the Company's self-imposed filing deadline. Celgene nevertheless chose to submit a facially incomplete NDA without the results rather than delay the filing. FE 22 had heard that Martin and Saillot "***just wanted to get the NDA out the door***." FE 20 echoed FE 22's account, explaining that the Ozanimod NDA had been "***hustled forward***."

211. Celgene's decision to push ahead with a facially deficient NDA submission which lacked the required Metabolite test results was motivated by two principal factors. First, as discussed above, Celgene was motivated to submit the NDA prematurely in order to begin marketing Ozanimod and gain market share before generic versions of Gilenya began to enter the market in 2019.

212. Second, many of Celgene's high-ranking employees were entitled to receive bonuses upon mere submission of the NDA to the FDA. FE 22 recounted that both Martin and Saillot received bonuses for submitting the Ozanimod NDA by year-end 2017. FE 20 similarly confirmed that the compensation for the Celgene and Receptos personnel, including Martin, was tied to the Ozanimod NDA filing. FE 20 explained that this was the "carrot" for the employees,

and the higher one went up the corporate chain, the greater the amount of compensation tied to the NDA filing. Confirming these accounts, as set forth in Celgene's proxy statement filed with the SEC in 2017, Hugin, Alles, Kellogg and Smith were all entitled to performance awards based in part on the "filing of a new drug application." Notably, Hugin, Alles, Kellogg, and Smith received lucrative performance awards for 2017 of $2,175,000, $2,144,623, $800,352, and $845,495, respectively, along with company stock.

213. In the months following Celgene's Ozanimod NDA filing, Defendants continued to tout the NDA submission and expected FDA approval, while withholding from investors material adverse information regarding the Metabolite and the Company's decision to submit the NDA without the requisite test results, even though the FDA told the Company in November 2017 that such results were required for approval. For example, on January 8, 2018, Celgene filed a press release in a Form 8-K with the SEC that identified the "FDA decision on the submission of an NDA for ozanimod in patients with relapsing multiple sclerosis (RMS)" as a "2018 Expected Operational Milestone[]." Similarly, despite the great concern that arose when Celgene found the Metabolite in November 2016 and Celgene's decision not to perform the required testing prior to its NDA submission, the Company highlighted other testing results on a January 25, 2018 Form 8-K, but made no mention of the Metabolite and the further Phase I testing required for FDA approval. As Celgene stated: "In December, a New Drug Application (NDA) was submitted with the FDA for ozanimod in relapsing multiple sclerosis (RMS) based on data from the phase III RADIANCE Part B and SUNBEAM trials evaluating ozanimod in patients with RMS."

6. The FDA Refuses to File the Ozanimod NDA

214. On February 27, 2018, Celgene once again stunned the market by disclosing that it had received an RTF letter in response to its Ozanimod NDA submission.

215. The FDA can refuse to file an NDA and issue an RTF letter if it identifies clear and obvious deficiencies in a company's submission. As the FDA's Standard Operating Policy and Procedure ("SOPP") explains:

> ***[A]n RTF is based on omissions of clearly necessary information*** (e.g., information required under the statute or regulations) or omissions or inadequacies so severe as to render the application incomplete on its face and where the omissions or inadequacies are obvious, at least once identified, and not a matter of interpretation or judgment about the meaning of data submitted.

216. The SOPP provides that an RTF "[i]s not an appropriate vehicle for dealing with complex issues and close judgments on such matters as balancing risks and benefits, magnitude of clinical effect, acceptability of a plausible surrogate marker, or nuances of study design." Instead, an RTF is based on "***[s]cientific incompleteness, such as omission of critical data, information or analyses needed to evaluate safety, purity and potency or provide adequate directions for use***." Thus, an RTF indicates the FDA's threshold rejection of an NDA based on facial inadequacies identified through a summary review of the NDA's contents, rather than an in-depth, all-encompassing review of the substantive data and information underlying the submission. In other words, receipt of an RTF letter sends a clear message that the identified deficiency is patently obvious and that the NDA should never have been filed in the first place.

217. There is little publicly available information regarding the frequency of RTF letters because the FDA does not release information on the subject and companies do not necessarily disclose their receipt of RTFs. However, the limited available information suggests that RTF letters are exceedingly rare. For example, using the subscription data service BioMedtracker, *Forbes* reported that the FDA issued just forty-five RTF letters in connection with NDA applications in the sixteen-plus years between December 31, 2001 and February 28, 2018. Moreover, receipt of RTFs by experienced and well-capitalized pharmaceutical companies like Celgene is virtually unheard of. As William Blair stated in a report entitled,

"While Not a Crisis for Ozanimod, FDA's RTF Letter Represents Another I&I Franchise Setback and Could Lead to a One-Year Delay," published in the wake of the FDA's RTF for Ozanimod: "In our view, well managed and high quality large-cap biotech companies do not make execution mistakes like the one disclosed on Tuesday [by Celgene]."

218. Celgene broke the news of the RTF letter to investors in a press release on February 27, 2018, stating: "Upon its preliminary review, the FDA determined that the nonclinical and clinical pharmacology sections in the NDA were insufficient to permit a complete review."

219. Analysts expressed both shock and concern upon the Company's revelation of the RTF. For example, Leerink Partners noted in a report entitled "How Many Self Inflicted Wounds Are Excusable? Ozanimod Delay at Least a Year," that the RTF "only adds to investors' growing unease with the company's direction and oversight of key activities" and observed that "***the company clearly made a decision to file this application at risk***, despite late information that might have been more thoroughly disclosed and explored in the application, had the filing been postponed by a few months." As Leerink Partners further explained:

> Celgene appears to have ***gambled on the ozanimod filing in December 2017*** while knowing about the unanticipated finding from a late-stage clinical pharmacology trial [i.e., the Mass Balance Study] after the two phase IIIs read-out successfully. ***This study seemed to duplicate the type of study that would originally have been completed by Receptos, and the completion of the study itself suggests some recognition of a deficiency in the early clinical package prepared by the prior owner***.

220. William Blair also wrote: "Obviously, investors are frustrated by another setback in the autoimmune franchise, especially in light of late last year's mongersen failure in Crohn's disease, clinical delay for ozanimod in ulcerative colitis, and soft third-quarter sales for Otezla."

221. In the wake of the RTF announcement, the price of Celgene's common stock fell from $95.78 per share on February 27, 2018 to $87.12 per share on February 28, 2018.

Defendant Smith, who had been promoted from head of I&I to COO in April 2017, was ushered out of Celgene in April 2018. George Golumbeski, Celgene's head of business development who was lauded as the chief architect of Celgene's acquisition strategy, also left the Company in April 2018. In addition, Defendant Martin was relieved of his responsibilities at Receptos in June 2018 and, according to FE 22, the employees within Martin's command at Receptos were let go after Celgene received the RTF. Furthermore, the 2018 proxy statement removed the "filing of a new drug application" as a factor in deciding upon senior management performance awards.

7. Celgene Admits that the RTF Was Due to Its Failure to Properly Test the Metabolite

222. On April 25, 2018, several scientists gave a presentation at the American Association of Neurology ("AAN") 2018 Annual Meeting in Las Vegas, Nevada entitled "Safety of Ozanimod Versus Interferon (3-1a in Two Multicenter, Randomized, Double-Blind, Parallel-Group, Active-Controlled, Double-Dummy Phase 3 Studies in Relapsing Multiple Sclerosis (SUNBEAM and RADIANCE Part B)." This presentation, which was partially funded by Celgene, disclosed to investors certain specifics of the Metabolite, dubbed CC-112273 by the Company, stating that: "Ozanimod is metabolized in humans to form one major active and other minor active metabolites"; "CC112273 accounts for the majority of the total activity of ozanimod in humans"; and "CC112273 is a minor metabolite in animal species."

223. Just days after the 2018 AAN annual meeting, the market learned that the additional preclinical work required to test the Metabolite could delay Celgene's refiling of its Ozanimod NDA for ***up to three years***. This is precisely the kind of significant delay that the FDA guidance cautions that drug companies should avoid by conducting the required metabolite safety testing early, before NDA submission. Specifically, on April 29, 2018, Morgan Stanley

published a report entitled "More Bread Crumbs Yield Less Confidence In Ozanimod" that provided a detailed analysis comparing the recently disclosed information regarding the Metabolite to the data from the Company's earlier pre-clinical studies involving Ozanimod's other metabolites. This analysis demonstrated that Celgene would need to run additional pre-clinical toxicology studies, which could take six months to two years. Thus, when combined with the time needed to start the studies, produce the study results and refile the NDA, these additional studies would result in a total delay of one to three years. In response to the news of a further delay, Celgene's common stock fell from $91.18 per share on Friday, April 27, 2018 to $87.10 per share on Monday, April 30, 2018, the next trading day.

224. During its first quarter 2018 conference call on May 4, 2018, Celgene confirmed that the RTF arose as a result of the Metabolite and that Celgene discovered the Metabolite through the Mass Balance Study in November 2016. Jay Backstrom, Celgene's Chief Medical Officer, stated, in part: "[T]he key issues for the Refusal to Rile centered on the completeness of the clinical pharmacology and the nonclinical portions of the NDA. These issues relate to the major active metabolite, CC-112273." Specifically, Backstrom stated that the Company conducted "a radio-labeled human mass balance study" that "identified CC-112273 as a major metabolite, accounting for approximately 90% of the activity" and that CC-112273 "disproportionately formed in humans and was not identified as a major metabolite in the nonclinical [i.e., animal] pharmacology studies." Backstrom further revealed that the half-life of the Metabolite is ***ten to thirteen days***, compared to the previously reported Ozanimod half-life of nineteen hours, thus confirming that Ozanimod had lost one of its key competitive advantages over Gilenya.

225. Celgene admitted that, upon review of the Ozanimod NDA, the FDA "requested further characterization of CC-112273." Alles claimed to be surprised by the FDA's decision, stating that: "[T]he hindsight view is that the characterization of [the] metabolite was something that we simply underestimated in the context of FDA's decision." FE 2, however, rejected Defendants' claims, stating that, based on his experience with more than five NDA submissions, it was "incomprehensible" that Celgene was surprised by the FDA's interest in the Metabolite.

226. In explaining the Company's plan for Ozanimod going forward, Backstrom stated that after the Company's meeting with the FDA in early 2018, Celgene planned to utilize data from the existing and ongoing clinical pharmacology studies to provide the requisite safety assessment for the Metabolite. Backstrom also attempted to reassure investors: "***This work is well underway and will be incorporated into a new submission now targeted for Q1 2019***."

227. Following Celgene's first quarter 2018 conference call, analysts and other commentators condemned Celgene for its decision to file the NDA without adequate characterization of the Metabolite. An *In the Pipeline* article entitled "Finger-Pointing at Celgene," questioned: "[W]hy wasn't [the] issue [of the Metabolite] fully addressed for the FDA?" The article stated that Celgene should have discovered the Metabolite during Phase I testing:

> Analyzing blood levels of the parent compound and metabolites is one of the biggest points of Phase I, actually, so it's not like this could have been overlooked. If you find out that what you thought was your drug is apparently just a prodrug for what's really working *in vivo*, well, you have more work to do. ***But it appears that lack of data about the metabolite could have been one of the main reasons the FDA found the NDA unworkable, which just makes no sense***.

8. Celgene Attempts to Blame Receptos for the RTF

228. In an effort to deflect criticism for the RTF debacle away from Celgene itself, Defendants blamed Receptos for the deficient NDA filing, but in doing so, admitted that they knew the NDA was faulty upon submission. Specifically, Ahmed stated in a June 13, 2018

Financial Times article that "***I think that 99 percent of folk[s] at Celgene wouldn't have submitted [the NDA],*** but we had Receptos out on the West Coast and, for whatever reason, the decision was made to submit . . . . We learned a lesson of humility and that when you do an acquisition it's better to be more integrated rather than be completely away from the mothership." Ahmed's comments, which confirmed that Celgene knew that its NDA filing was deficient prior to submission, thoroughly undermined Alles' representation to investors that the FDA's focus on the Metabolite was unanticipated and something that the Company "underestimated." Ahmed also stated that FDA officials were "actually quite surprised" with the deficient quality of the Ozanimod NDA and that "[the FDA] kinda said 'what happened guys, this isn't what we usually expect from Celgene?' And we had to say, you know, '***mea culpa, it's on us***.'"

229. The former CEO of Receptos, Faheem Hasnain ("Hasnain"), quickly disputed Ahmed's attempt to place all the blame on Receptos and leave Celgene unscathed. Hasnain emphasized to the market that "[i]t's important to know that ***Celgene had on-site control and oversight for two-and-a-half years before this filing took place***," and made clear that at the time of Celgene's acquisition of Receptos in mid-2015, Receptos "had mapped out the rest of the development and regulatory plans, with the rest of the pharmacology studies that needed to be done in a timely fashion." Hasnain's comments were echoed by Frohna, the former Vice President of Clinical Development and Translational Medicine at Receptos, who was "responsible for conducting positive Phase 2 clinical trials and two ongoing Phase 3 trials with Ozanimod in relapsing multiple sclerosis (RMS) and ulcerative colitis." In a user comment responding to the article in which Hasnain was quoted, Frohna stated: "***Thanks for setting the record straight Faheem! You beat me to it*** . . . ."

230. FE 21 and his colleagues were not surprised by what they called the "bullshit blame game" that followed the RTF. FE 21 further stated that the idea that the final NDA submission could be made without the approval of Celgene's leadership was nonsensical. Likewise, FE 22 explained that the NDA would not have been submitted without the approval of Celgene headquarters, as it was too important a decision to be made at the Receptos executive level. FE 2 also rejected Celgene's attempt to cast blame on Receptos.

231. FE 20 further confirmed that Celgene's statements attempting to shift blame to Receptos for the RTF were empirically false, stating that "they [Celgene] were in charge. Receptos was not." FE 20 added that when Celgene acquired Receptos, Celgene moved in and took over, installed a new head of Receptos, had control over Receptos' budget, took Receptos out of the decision-making loop, placed Receptos under the control of Celgene's New Jersey headquarters, and decisions were made by Celgene in New Jersey or Celgene personnel located onsite at Receptos.

232. Celgene did not even refile an NDA for Ozanimod until March of ***2019***. The Company still has not completed the required testing of the Metabolite. For example, the "Drug-drug Interaction Study of Ozanimod with Inhibitor or Inducer of CYP2C8 and/or CYP3A," a study evaluating the potential for drug interactions with Ozanimod and the Metabolite, which is specifically contemplated by the FDA's Drug Interaction Guidance, was not completed until after February 27, 2019. Accordingly, the necessary Phase I testing was not completed until more than one year after the Company repeatedly and unwaveringly assured investors that Celgene would obtain approval of the Ozanimod NDA.

V. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

233. During the Relevant Period, Defendants made a series of materially false and misleading statements and omitted material facts regarding: (i) Otezla's ability to gain market acceptance and meet the Company's 2017 financial guidance, and (ii) the completeness of the Ozanimod NDA for MS, the sufficiency of the underlying testing data, and the undisclosed discovery of a key, active metabolite that required further testing.

A. OTEZLA

234. On September 12, 2016, Celgene participated in the Morgan Stanley Global Healthcare Conference. During this conference, Smith talked at length about Otezla, stating, in response to an analyst question about the pricing of Otezla, that "[w]e believe that we should increase price ***and we've got the value and the data to support increasing utilization, and increasing value***."

235. Analysts took note. For instance, following the Morgan Stanley Global Healthcare Conference, Argus Research stated in a September 16, 2016 report: "We like Celgene's long-term prospects. The company has generated solid growth from its portfolio of pharmaceuticals and has a robust new product pipeline… With sales growing at a triple-digit rate, Otezla, for plaque psoriasis and psoriatic arthritis, may soon join Revlimid as a growth driver."

236. The statement set forth in ¶ 234 above was materially false and misleading, omitted material facts, and lacked a reasonable basis when made. Specifically, as set forth in ¶¶ 92-155 above, at the time Defendant Smith made this statement, he knowingly or recklessly concealed and/or failed to disclose that:

(i) Defendants' Otezla pricing strategy ensured that Celgene would never attain the growth in sales and revenues necessary to meet the 2017 guidance;

(ii) Celgene sales representatives from across the country were reporting flat Otezla sales growth from the date of the drug's March 2014 launch;

(iii) Otezla was plagued by issues including step-edits, poor insurance coverage, and inferior efficacy compared to competitors that impaired its sales, ability to raise prices, and attendant revenues;

(iv) during the third and fourth quarters of 2016, Smith, Curran, and other members of the IIEC and CPMAC, were explicitly warned by both Celgene's Senior Vice President of I&I and a senior executive in the U.S. Market Access group that Celgene could not meet the 2017 Otezla guidance and that these numbers should be lowered;

(v) FE 17 recounted that the Forecasting team was "told to change" the numbers (i.e., the internal forecasts) by Smith and Curran to conceal the lack of growth; and

(vi) FE 18, confirmed that when Defendants were assessing the 2017 Otezla market access and setting the 2017 targets, the market did not support even close to 57% growth.

By electing to speak publicly about Celgene's pricing strategy with respect to Otezla, and the data underlying that strategy, and thereby putting these subjects into play, Defendant Smith had a duty to fully, completely, and truthfully disclose all material facts regarding that strategy and regarding the fact that Celgene was not positioned to meet the 2017 guidance and that this guidance could not be met given the numerous issues impacting Otezla revenues, including the consequences of Celgene's pricing strategy. As a result of the foregoing undisclosed material facts, Defendant Smith's public statement lacked a reasonable basis and was materially false and misleading at all relevant times.

237. On April 27, 2017, Celgene filed a Form 8-K with the SEC announcing certain first quarter 2017 operating and financial results. That same day, Celgene hosted a conference call to discuss the Company's financial results for the first quarter of 2017. During that

conference call, in responding to a request from a UBS analyst that the Company "walk through what gives you confidence [that Otezla] growth will bounce back," Curran stated:

> I think there was really 3 key drivers to the performance in the first quarter. Firstly, we saw contraction in the market as we saw increased [gross to net] as a result of the contracting. But importantly, that really gives us access to double the number of insured lives going forward. And lastly, we saw a minimal drawdown in inventory. ***Importantly, if we look at the underlying dynamics of the business, they're exceptionally strong.*** If you look at the market share, OTEZLA continues to grow market share. We continue to gain more than 40% of new patients. And these new contracts will give us access to an additional pool of patients moving forward. Importantly, if we look at the exit run rates out of quarter 1 and into quarter 2, ***we do see the net sales rebounding and on track to deliver our 2017 guidance.***

238. Analysts seized on Defendants' reaffirmation of the 2017 Otezla guidance and statements touting the "underlying dynamics of the business" in their April 27, 2017 conference call notwithstanding the first quarter miss. For example, BMO Capital Markets noted in an April 27, 2017 report that: "Management reiterated FY2017 Otezla sales of $1.5-1.7bn." UBS stated in an report issued the same day that "Celgene reiterated confidence in achieving 2017 guidance and the longer term outlook for Otezla, citing consistent market share growth (>40% of new patients), narrowing its position behind Stelara in the psoriasis market, and new contracts that increase market access and share" and an April 28, 2017 JM? Securities report observed: "We note that previous guidance of $1.5bil to $1.7bil in net Otezla sales for 2017 remains intact despite this soft quarter."

239. The statements set forth in ¶ 237 above were materially false and misleading, omitted material facts, and lacked a reasonable basis when made. Specifically, as set forth in ¶¶ 92-155 above, at the time Defendant Curran issued this statement, Defendants knowingly or recklessly concealed and/or failed to disclose that:

(i) Defendants' Otezla pricing strategy ensured that Celgene would never attain the growth in sales and revenues necessary to meet the 2017 guidance;

(ii) Celgene sales representatives from across the country were reporting flat Otezla sales growth from the date of the drug's March 2014 launch;

(iii) Otezla was plagued by issues including step-edits, poor insurance coverage, and inferior efficacy compared to competitors that impaired its sales and attendant revenues;

(iv) during the third and fourth quarters of 2016, Smith, Curran, and other members of the IIEC and CPMAC were explicitly warned by both Celgene's Senior Vice President of I&I and a senior executive in the U.S. Market Access group that Celgene could not meet the 2017 Otezla guidance and that these numbers should be lowered;

(v) FE 17 recounted that the Forecasting team was "told to change" the numbers (i.e., the internal forecasts) by Smith and Curran to conceal the lack of growth;

(vi) FE 18 confirmed that when Defendants were assessing the 2017 Otezla market access and setting the 2017 targets, the market did not support even close to 57% growth;

(vii) Defendants' decision to allow wholesalers to buy Otezla in excess of their demand in the fourth quarter of 2016 negatively impacted the first quarter 2017 Otezla sales;

(viii) Tessarolo, Senior Vice President of I&I, U.S., had again warned Defendants in early 2017 that the Company needed to downgrade its 2017 Otezla revenue guidance;

(ix) the newly-entered PBM contracts Defendants claimed "doubled the number of patient lives who can now access OTEZLA without being required to step through a biologic therapy" would not positively impact Celgene's Otezla net product sales for months or even years; and

(x) FE 18 recounted that it was clear from the beginning of 2017, based on the models that his team was running monthly, that the PBM contracts were not meeting revenue expectations and Celgene eventually lowered the expectations on many of these PBM contracts internally.

By electing to speak publicly about Celgene's 2017 Otezla sales guidance and the underlying dynamics of the business—and thereby putting this subject into play—Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding the fact that Celgene was not positioned to meet the 2017 guidance, and that this guidance could not be met given the numerous issues impacting Otezla revenues. As a result of the foregoing undisclosed material

facts, Defendant Curran's public statements lacked a reasonable basis and were materially false and misleading at all relevant times.

B. OZANIMOD

240. As detailed above in ¶¶ 183-184, by no later than November 21, 2016, Defendants discovered the Metabolite. Former employees referred to the finding as a great concern, which required additional, time-consuming Phase I testing which would prevent the filing of a complete NDA in 2017. The former employees also stated that the submission of the NDA for Ozanimod without the testing would lead the FDA to reject the NDA and issue an RTF (which the FDA did). In the face of these and other undisclosed material facts, Defendants issued the following material misrepresentations and omissions during the Relevant Period.

241. On April 27, 2017, Celgene hosted a 2017 conference call to discuss the Company's first quarter 2017 financial results. In connection with the April 27, 2017 conference call, Celgene issued and published a series of slides on its corporate website. One of the slides, entitled "2017 I&I Franchise Outlook," was presented by Defendant Smith. This slide, which is shown below, touted "Advancing Ozanimod Development Programs in MS and IBD" and confirmed that Celgene would "***submit ozanimod U.S. NDA in RMS [in 2017]***."

242. In reporting on Celgene's April 27, 2017 conference call, analysts focused on Defendants' representations that Celgene would submit an NDA by year-end 2017. For example, Barclays stated in an April 27, 2017 report that "[n]otably, Celgene plans to submit an NDA in RMS by year-end, with a likely launch in 2018." J.P. Morgan similarly stated in an April 27, 2017 report that a "Key 2017 catalyst[]" included "Ozanimod Ph3 data in MS in May with NDA submission by YE17" and Oppenheimer acknowledged in an April 27, 2017 report that "Celgene announced it intends to file Ozanimod for regulatory approval by the end of 2017 using data from the phase III SUNBEAM and RADIANCE studies."

243. The statement set forth in ¶ 241 above, including the statement that the Celgene was set to file the Ozanimod NDA by the end of 2017, were materially false and misleading, omitted material facts, and lacked a reasonable basis when made. Specifically, as set forth in ¶¶ 156-232 above, at the time Defendant Smith issued these statements, Defendants knowingly or recklessly concealed and/or failed to disclose that:

(i) Defendants discovered a disproportionate Metabolite in November 2016;

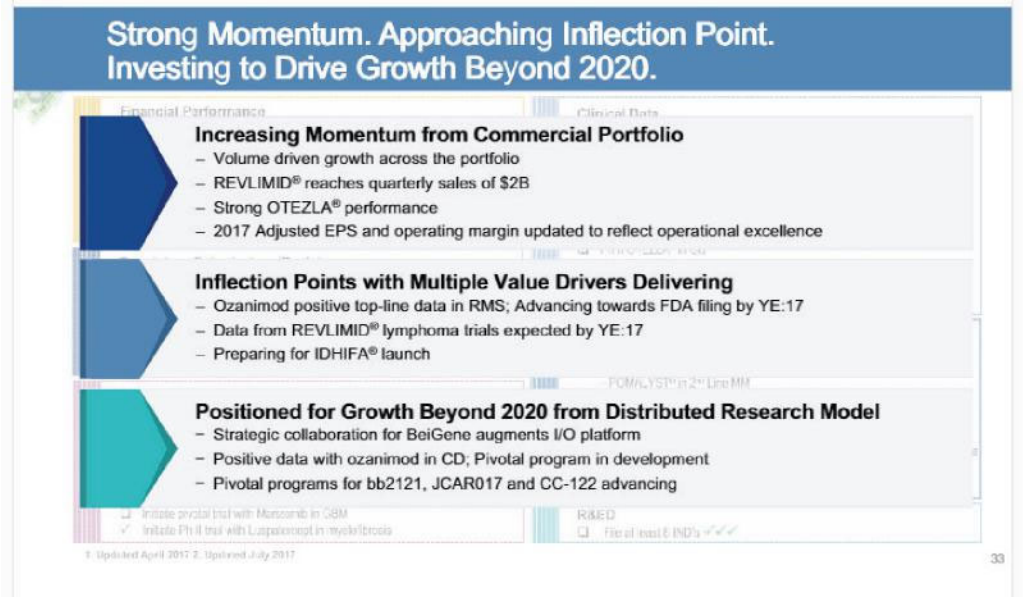
(ii) the testing and studies regarding the Metabolite, including many Phase I studies, that needed to be conducted prior to filing the NDA put the Company's NDA filing timeline at risk and rendered it unreasonable; and

(iii) if Celgene submitted the NDA without the necessary metabolite testing and studies, the FDA was almost certain to issue an RTF.

By electing to speak publicly about the complete status of Celgene's Ozanimod Phase III studies and the Company's professed ability to submit a complete NDA for Ozanimod in 2017 for FDA approval in 2018, and thereby putting these subjects into play, Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding the discovery of the Metabolite and the need for additional Phase I testing that jeopardized Celgene's filing of a complete Ozanimod NDA in 2017 and Celgene's ability to receive FDA approval in 2018, so as to not mislead investors. As a result of the foregoing, undisclosed material facts, Defendant Smith's public statements lacked a reasonable basis when made and were materially false and misleading at all relevant times.

244. On July 27, 2017, Celgene hosted a conference call and, in connection with that call, issued and published a series of slides on its corporate website. During that conference call, Defendant Smith confirmed that the study data from the Ozanimod testing was universally positive, stating "[j]ust to add on to the comments, ***we feel very, very good about the data that's emerging for ozanimod and looking forward to getting it out***."

245. Smith then presented a slide that discussed Ozanimod as having "***positive top-line data in RMS***" while "***[a]dvancing towards FDA filing by YE:17.***"



246. On October 26, 2017, Celgene also hosted a conference call to discuss the Company's third quarter 2017 financial results. In connection with that conference call, Celgene issued and published a series of slides on its corporate website. One of these slides, presented by Defendant Smith, characterized Celgene's "***[o]zanimod FDA filing in RMS by YE:17***" as an inflection point in 2017 that would drive growth for Celgene.

247. Following Defendants' October 26, 2017 statements, analysts and other media outlets again reiterated Defendants' representations regarding Celgene's timeline for submission

of the Ozanimod NDA. For example, BTIG Equity Research stated in an October 26, 2017 report: "We expect ozanimod to be ***approved*** for MS during 2112018 (US NDA sub for [R]MS YE2017)." The Dow Jones Institutional News reported in an October 26, 2017 article: "Celgene plans to submit a New Drug Application (NDA) to the FDA for ozanimod in RMS by year-end."

248. Two days later, on October 28, 2017, Celgene held an Investor Event at the MSParis2017-7th Joint American-European Committee for Treatment and Research in Multiple Sclerosis. During this event, the Individual Defendants issued misrepresentations concerning Ozanimod. For example, in discussing the Ozanimod "development program," Defendant Martin stated:

> [T]he RADIANCE study and the SUNBEAM study will form the basis of our submission to the FDA and to [the] EMA. ***For the FDA, we are working hard as we speak to get ready to file by the end of the year***.

249. Defendant Smith stated:

> ***We announced positive top line data to ozanimod and SUNBEAM and RADIANCE earlier in the year***, and we've been very anxiously awaiting, getting to this meeting and being in a position to really get in and dig in and talk about the data. ***We're tremendously thrilled with the data and satisfied and happy***.
>
> * * *
>
> So it's very, very exciting for us to be heading off in this new venture in neurology, but heading off with such an amazing, potential cornerstone product as ozanimod with what we think is a ***very, very, very positive data***.
>
> * * *
>
> Since we went and made the acquisition and we've just continued to get more excited and more excited as we've continued to have data and whether that data was in MS and pivotal data, you see data firming up long term in the Phase II data, Crohn's data coming in. The data around this asset is very, very solid, and it's really, really exciting.

250. In reporting on Defendants' statements at the MSParis2017 meeting, Oppenheimer focused on Defendants' repeated representations regarding the Phase III trial data

and NDA submission timeline, stating: "Celgene has previously announced that further analyses of the RADIANCE trial are ongoing and it plans to submit an NDA to the FDA, based on the combined SUNBEAM and RADIANCE trials for relapsing MS by the end of 2017."

251. The statements set forth in ¶¶ 244-250 above, including Defendants' statements that the Phase III studies for Ozanimod were positive and complete and that, in light of these study results, Celgene was set to file the Ozanimod NDA by the end of 2017, were materially false and misleading, omitted material facts, and lacked a reasonable basis when made. Specifically, as set forth in ¶¶ 156-232 above, at the time Defendants issued these statements, Defendants knowingly or recklessly concealed and/or failed to disclose that:

(i) Defendants discovered a disproportionate Metabolite in November 2016;

(ii) the testing and studies regarding the Metabolite, including many Phase I studies, that needed to be conducted prior to filing the NDA put the Company's NDA filing timeline at risk and rendered it unreasonable; and

(iii) if Celgene submitted the NDA without the necessary metabolite testing and studies, the FDA was almost certain to issue an RTF.

By electing to speak publicly about the complete status of Celgene's Ozanimod Phase III studies and the Company's professed ability to submit a complete NDA for Ozanimod in 2017 for FDA approval in 2018, and thereby putting these subjects into play, Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding the discovery of the Metabolite and the need for additional Phase I testing that jeopardized Celgene's filing of a complete Ozanimod NDA in 2017 and Celgene's ability to receive FDA approval in 2018, so as to not mislead investors. As a result of the foregoing, undisclosed material facts, Defendants' public statements lacked a reasonable basis when made and were materially false and misleading at all relevant times.

252. As discussed above (*see* ¶¶ 202-213), Celgene submitted the Ozanimod NDA for

MS to the FDA in December 2017, notwithstanding that it omitted the Metabolite testing results demanded by the FDA at their November 2017 meeting with the Company.

VI. THE RELEVANT TRUTH EMERGES: ALLEGATIONS OF LOSS CAUSATION

253. Defendants' material misstatements and omissions complained of herein artificially inflated the market price of Celgene's publicly traded common stock. The artificial inflation in Celgene's stock price was removed when the facts and risks misstated and omitted by Defendants were revealed to the market. Such corrective information was disseminated to investors through public disclosures on October 26, 2017, February 27, 2018, and April 29, 2018. Each such disclosure partially revealed relevant facts regarding the false and misleading nature of Defendants' material misstatements concerning Otezla and Ozanimod. Each disclosure, more particularly described below, removed artificial inflation in the price of Celgene's publicly traded stock, causing economic injury to Plaintiff.

A. OCTOBER 26, 2017: CELGENE DISCLOSES SHARPLY NEGATIVE FINANCIAL RESULTS FOR OTEZLA

254. On October 26, 2017, the Company released is third quarter 2017 financial results. Celgene reported total Otezla sales of only $308 million, a 14% decline from second quarter 2017 Otezla sales, and blamed "an increase in gross-to-net adjustments from contracts implemented in January and a slowing in overall category growth due to a more challenging market access environment." Celgene also announced that it no longer expected 2017 Otezla net product sales to be between $1.5 billion and $1.7 billion as it had previously stated, but rather expected 2017 sales to be only approximately $1.25 billion. Celgene also stated that it was lowering its fiscal 2020 guidance as a result of the poor Otezla results.

255. In response to Defendants' disclosures on October 26, 2017, the price of Celgene common stock fell by $19.57 per share—more than 16%, from a close of $119.56 on October 25,

2017 to close at $99.99 on October 26, 2017 on abnormally high trading volume of 24.1 million shares. This wiped out more than $14 billion in Celgene market capitalization.

256. Analysts commented negatively not only on Celgene's missed and lowered guidance, but also on management's credibility. For instance, J.P. Morgan reported on October 26, 2017 that Celgene "management faces a major credibility issue." That day, Cowen and Company similarly reported that the shortfall on Otezla sales "is likely to impact the company's credibility." On October 26, 2017, *SeekingAlpha* also reported that "the Street has suddenly lost trust in Celgene's pipeline as well as the credibility of management's guidance." Raymond James downgraded Celgene stock from Strong Buy to Market Perform, and reported:

> ***[T]oday's update substantially alters our outlook and confidence in the company's ability to execute***. We previously viewed Celgene's immune & inflammatory (I&I) franchise as a key driver to facilitate a revenue diversification effort away from Revlimid. However, with GED-0301 now eliminated, and Otezla appearing to stumble, revised FY20 targets indicate an increasing reliance on the hematology franchise (rather than decreasing), which is the opposite of what we'd hope to see over time. Even if ozanimod data shows differentiation, we think CELG has now become a 'show me' story[.]

257. Piper Jaffray also reported on October 26, 2017 that "despite an attractive valuation, we think management will need to start executing better commercially, clinically and strategically before this stock begins to work again." Piper Jaffray further reported that:

> While some expected management to revisit 2020 guidance, given the GED-0301 failure from last week, we think ***the magnitude of the reset has clearly shaken investors***. Indeed, in one fell swoop, 2020 revenue guidance was shaved by $1.5B, with hematology accounting for >80% of revenue up from 70% of revenue. . . . With this new outlook, we can't imagine angst on this front will go away any time soon.

258. Similarly, BTIG Equity Research reported on October 26, 2017 that Celgene's third quarter results "***severely disappointed relative to expectations on Otezla***, and mgmt significantly lowered 2020 guidance due to several product forecast revisions." Jefferies Group LLC also reported that day that "***CELG put up an unusual notable revenue miss (it's been a***

few years since that happened by this much) and notably lowered 2017 revenue guidance and 2020 revenue and EPS guidance," and that "it will take some time to re-engage in credibility to hit targets and get quarters back on track and reset the situation."

259. Analysts also discussed the factors that drove Celgene's lower Otezla revenues. For example, in an October 26, 2017 report, BMO Capital Markets attributed the Otezla miss in part to discounting and competition from other psoriasis treatments, stating that "[a]lthough Otezla script growth was apparent (+4% Q/Q), it just wasn't enough to offset the aggressive discounting and slowing growth of psoriatic arthritis and ***greater competition*** in psoriasis markets."

260. Analysts reported that the magnitude of Celgene's miss was a surprise to the market. On October 26, 2017, J.P. Morgan reported that:

> In a word, CELG's print this morning was ugly. The company reported a top-line miss (total revenue of $3.28B vs. cons of $3.42B) with a bottom-line beat (non-GAAP EPS of $1.91 vs. cons of $1.87). . . . Otezla, in particular, was the standout for the wrong reasons with a bad miss ($380M vs. $411M). We believe a weak quarter was expected based on lackluster Rx trends, but not to this extent.

261. UBS similarly reported the same day that:

> While some shift in the makeup of 2020 guidance was expected (though not today), lowered guidance is a ***surprise*** – leaving the company even more dependent on Revlimid just as the focus on that[] drug['s] IP (rightly or wrongly) intensifies.

262. Also on October 26, 2017, Leerink Partners reported:

> This morning ***Celgene reported alarming Q3 2017*** with revenues 4% below consensus and pro forma EPS 2% above consensus, and the company lowered their long-term 2020 revenue targets by 5-10% after recent pipeline failures and negative market trends for Otezla. ***Investors are likely to ask whether the company's good fortune has run out, with disappointments (mongersen) and negative revisions (Otezla) left and right.*** Recently installed new management are likely to face tough questions from investors about the company's direction and leadership after the operational and guidance disappointments this quarter.

263. Despite Celgene's disclosures concerning Otezla results and related stock price decline, the price of Celgene common stock remained artificially inflated as Defendants continued to misrepresent and conceal material information from investors concerning Ozanimod. For example, during the October 26, 2017 conference call, Smith tried to reassure investors that Celgene was:

> also accelerating many high-value pipeline opportunities, which represent significant investments and opportunities that will enable us to reach our long-term goals. While we're disappointed with the discontinuation of the RESOLVE and SUSTAIN Crohn's disease trials in GED-0301, we remain steadfastly committed to the development of novel therapies for patients suffering from IBD. We are awaiting full data from GED-0301 in UC and have a robust portfolio of potentially transformative IBD assets in late-stage development, including OTEZLA UC and ozanimod in UC as well as Crohn's disease.

B. FEBRUARY 27, 2018 AND APRIL 29, 2018: CELGENE RECEIVES A REFUSAL-TO-FILE LETTER FOR OZANIMOD BASED ON ITS LACK OF METABOLITE TESTING

(a) February 27, 2018: Celgene Discloses the Refusal-to-File Letter for Ozanimod

264. After market close on February 27, 2018, just three weeks after Celgene's Form 2017 10-K touted the fact that "a New Drug Application (NDA) was submitted with the FDA for Ozanimod in RMS based on data from the phase III trials," Celgene issued a press release revealing that it had received an RTF from the FDA regarding its recently submitted NDA for Ozanimod. Celgene's press release stated:

> [U]pon its preliminary review, the FDA determined that the nonclinical and clinical pharmacology sections in the NDA were insufficient to permit a complete review. Celgene intends to seek immediate guidance, including requesting a Type A meeting with the FDA, to ascertain what additional information will be required to resubmit the NDA.

265. In response to the Company's disclosure on February 27, 2018, the price of Celgene common stock fell by $8.66 per share—more than 9%—from a close of $95.78 on February 27, 2018 to a close of $87.12 on February 28, 2018, on abnormally heavy trading

volume of 27.9 million shares. This disclosure wiped out more than $6.5 billion in market capitalization.

266. Analysts responded immediately and negatively to this news, expressing shock and disappointment, particularly given management's recent positive commentary on Ozanimod. On February 27, 2018, for example, Raymond James reported that the market "didn't see this one coming," and called the RTF news an "unexpected development." *SeekingAlpha* reported the same day that the news of Celgene's RTF was "hard to accept as a reality" because receiving such a refusal to file letter from the FDA is "almost unheard of for a major company." Credit Suisse similarly reported that "we are disappointed by the timing delay related to the filing, and we think that this will continue to further concerns associated with management execution."

267. Reflecting on the critical implications the RTF would have for Celgene, RBC Capital Markets reported on February 27, 2018 that "given that [Celgene] will be requesting a Type A meeting with the FDA, it may be some time before there is additional clarity on the potential path forward. We view ozanimod as one of the most, if not the most, important pipeline programs for CELG[.]"

268. Other analyst firms also reported on February 27, 2018 that the RTF raised questions about Celgene's ability to diversify away from Revlimid. For example, Piper Jaffray reported that:

> It's been a rough couple of months [for Celgene]. GED0301 failure notwithstanding, this isn't the first execution-related hurdle that I&I franchise has faced, with Otezla routinely falling short of expectations and the timeline for ozanimod in UC also recently delayed [], only raising more questions regarding CELG's efforts to diversify away from Revlimid.

269. Despite Celgene's disclosure of the RTF and the related stock price decline, the price of Celgene common stock remained artificially inflated as Defendants continued to conceal

material information from investors concerning the testing required to address the Metabolite and how that testing would affect the timeline for submitting the revised NDA.

(b) April 29, 2018: Investors Learn that the Resubmission of the NDA will be Delayed up to Three Years

270. After almost two months of speculation surrounding the RTF, on April 25, 2018, in a presentation of Phase III Ozanimod Multiple Sclerosis data at an AAN meeting, a Celgene investigator disclosed new information about a "major active metabolite" of Ozanimod (CC112273), which, in fact, is behind the vast majority of Ozanimod's efficacy. Specifically, the investigator disclosed that Celgene first identified the Metabolite in a human mass balance study conducted in parallel with the Phase III Ozanimod trials, that the Metabolite levels were much lower in the animal species used in the non-clinical studies than in humans, and that the Metabolite is responsible for approximately 90% of Ozanimod's clinical activity.

271. Despite Celgene's disclosure of the Metabolite on April 25, 2018, the price of Celgene common stock remained artificially inflated as Defendants continued to conceal material information from investors concerning the testing required to address the Metabolite and how that testing would affect the timeline for submitting the revised NDA.

272. The market's initial response to this news was mixed, as analysts tried to digest what it meant for Celgene and investors. For example, Morgan Stanley issued an analyst report after the close of trading on April 25, 2018 that concluded that the "Disclosure of active metabolite for Ozanimod is a ***net positive*** as it suggests the FDA RTF is due to lack of characterization of the metabolite." The analyst added that "[w]ith mgt. indicating it will provide an update with earnings and highlighting this disclosure at AAN, ***we suspect many investors will view this positively*** . . . ." As a result, Morgan Stanley wrote that it "would expect to see CELG ***up*** in the low-to-mid single digit % on the news."

273. The next day, April 26, 2018, RBC Capital Markets reported that "[t]hough we still do not know the exact reasons CELG received an RTF, the fact pattern suggested by yesterday's new details strongly indicates [the RTF] likely relates to ***some FDA discomfort*** around the characterization of this metabolite []" but that "[w]hether this can be quickly rectified, perhaps with add'l clinical characterization remains the key question and ***the key unknown***."

274. The ambivalence came to an end on Sunday, April 29, 2018, after Morgan Stanley issued a strongly negative report based on its detailed review of certain obscure data related to Ozanimod's other metabolites. Morgan Stanley's April 29, 2018 report entitled, "More Bread Crumbs Yield Less Confidence in Ozanimod," stated that its "analysis of prior ozanimod pre-clinical studies suggest [that] CC112273 concentrations in prior pre-clinical work is unlikely to approximate human clinical doses" and, "[t]herefore we believe it is increasingly likely mgt. will need to complete new preclinical work on CC112273 ***setting up a 1 to 3 year delay***."

275. The Morgan Stanley analysts explained that their analysis was only made possible after they "were able to locate copies of [] posters over the weekend [April 28 and 29]" containing the "previously published ozanimod preclinical toxicology results and studies of [the two] known metabolites," i.e., other than CC112273. The posters established that the two previously identified metabolites produced levels in the animal studies that were just above the human therapeutic dose and therefore approximated the human dose. The analysts further explained that, based on their review of FDA guidance on metabolites, "the only way for mgt. to avoid synthesizing CC112273 and re-running preclinical [i.e., Phase I] toxicology [i.e., engaging in protracted testing] was by having exposure of CC112273 in animals equivalent to the human therapeutic dose" so that Celgene could simply recycle the prior testing used on the known metabolites. However, as Morgan Stanley explained, a "1 to 3 year delay" in completing the

requisite testing was unavoidable given the significantly higher levels of the Metabolite in humans compared to animals. Morgan Stanley referred to its "prior review of FDA guidance on metabolites" and stressed that:

> However, given that mgt. indicated 'CC112273 levels were ***much lower*** . . . in the animal species used in the non-clinical studies than the amount produced by humans' and that ***our calculations suggest the prior set of identified (and thus studied metabolites) produced levels barely above the human therapeutic dose, we believe it is increasingly unlikely CC112273 produced levels near the human therapeutic dose in the prior preclinical work. Thus, mgt. will likely need to re-run preclinical toxicology which could take 6 months (rats) to 2 years (another carcinogenicity study). Given the timeline to start the study, produce the study reports and refile, we believe the delay is at a minimum 1 year and up to 3 years if mgt. must redo all animal work.***

The bolding and italics above appeared in the original Morgan Stanley April 29, 2018 report, to emphasize the importance of this text to its readers.

276. Celgene's stock price fell on the news of the significant additional testing required from Celgene and the significant delay for Ozanimod approval as a result of the Company's premature submission of the NDA. Specifically, Celgene's common stock dropped from a close of $91.18 on April 27, 2018 to close at $87.10 on April 30, 2018, a 4.5% decline that wiped out approximately $3 billion in market capitalization.

277. Analysts attributed this decline to the revelations that resulted from Morgan Stanley's detailed, specialized analysis and digestion of Celgene's informationally-complex AAN disclosure. For example, *The Motley Fool* wrote on April 30, 2018 that: "[S]hares of Celgene lost 4.5%. The biotech giant got negative comments from analysts at Morgan Stanley, who predicted that it could take several years for Celgene to move forward with plans to file for approval from the U.S. Food and Drug Administration for its multiple sclerosis candidate drug ozanimod." Similarly, *Citywire* reported on the same day that "Celgene shares fell 4.5% after Morgan Stanley said it expects a delay of up to three years for Celgene's key multiple sclerosis

drug, ozanimod." Likewise, *Marketwatch* reported on this date that "Celgene Corp. . . . fell 4.5% after a Morgan Stanley report predicted a one- to three-year delay on any new attempt to file for U.S. approval of the company's highly anticipated drug ozanimod, which is designed to treat multiple sclerosis."

278. As a result of Defendants' misstatements and omissions, which were corrected by the disclosures discussed above, in total, the price of Celgene common stock ended the Relevant Period at $87.10, more than 40% below its Relevant Period high of $146.52 on October 4, 2017.

VII. ADDITIONAL ALLEGATIONS OF SCIENTER

279. Celgene and the Individual Defendants were active and culpable participants in the fraud, as evidenced by their knowing or reckless issuance of and/or control over Celgene's and the Individual Defendants' materially false and misleading statements and omissions. Celgene, through its management and other senior level employees, and the Individual Defendants acted with scienter in that they knew or recklessly disregarded that the public statements set forth in Section V above were materially false and misleading when made, and knowingly or recklessly participated or acquiesced in the issuance or dissemination of such statements as primary violators of the federal securities laws. In addition to the facts alleged in Section IV above, regarding Celgene's and the Individual Defendants' personal knowledge and/or reckless disregard of the materially false misrepresentations and omissions, Celgene's and the Individual Defendants' scienter is evidenced by the specific facts discussed below.

A. DEFENDANTS' KNOWLEDGE AND RECKLESS DISREGARD OF MISSTATEMENTS REGARDING OTEZLA AND OZANIMOD

280. Defendants were directly involved in and participated in both the management and day-to-day operations of the Company at its highest levels. Accordingly, as detailed below, Defendants each had access to detailed information concerning the Company's I&I franchise

generally, and Otezla and Ozanimod, specifically. This information was transmitted and learned through meetings, reports and other regular communications, as detailed by numerous confidential witnesses.

1. Otezla

281. Celgene's and the Individual Defendants' scienter with respect to the misstatements and omissions regarding the unreasonableness and unattainability of the Company's 2017 Otezla sales guidance is evidenced by the following facts, among others:

(a) Smith, Curran and others in senior management were warned that the 2017 Otezla sales guidance could not be met and should be lowered

(i) FE 7 repeatedly warned Defendant Smith that the Company's strategy of offering deep discounts and rebates for Otezla was fatally flawed and rendered it "impossible" for the Company to achieve the 2017 Otezla guidance. ¶ 136. As early as the Otezla launch, FE 7 informed Smith—who had the final say with regard to Otezla and Market Access decisions—that he would be destroying the "best price" for the drug by offering large rebates and discounts, thereby setting Otezla up for consistently depressed net revenues going forward. ¶¶ 98-100.

(ii) FE 7 wrote multiple emails to Celgene's senior executive management, including Smith, documenting his concerns about the discounts and rebates that Celgene was offering for Otezla. ¶ 101. FE 7 also told Smith that Celgene should never "pay to play"—i.e., offer rebates and deep discounts in exchange for market access, as that would prevent Celgene from maximizing its profits. ¶ 101.

(iii) According to FE 14 and FE 12, Celgene's management had access to Otezla sales data that Celgene received from IMS through Tableau. This data reflected straight volume, volume growth, number of prescriptions by territory, number of prescriptions by provider, and number of prescriptions attributed to each salesperson. ¶ 105. Sales representatives from across the country all reported that sales of Otezla, which were reflected in Tableau, were steady to flat from 2014 through 2017. ¶¶ 104-105.

(iv) No later than the third quarter of 2016, Tessarolo communicated in weekly meetings with the IIEC, which included Defendants Smith and Curran, that the 2017 Otezla guidance could not be met. ¶ 122.

(v) During presentations in the third and fourth quarters of 2016, FE 17 and his team informed the IIEC that the 2017 Otezla sales guidance could not be met. FE 17 recounted that "***everyone knew that the actual stated forecast was not reasonable***" and could not be met. ¶ 121-23.

(vi) In the fourth quarter of 2016, FE 17 expressly advised the IIEC that the Otezla sales guidance should be lowered. ¶ 123.

(vii) By the end of 2016, Tessarolo again warned the IIEC of the need to lower the 2017 Otezla sales guidance, but the IIEC insisted that the forecasts would not be changed. ¶ 123.

(viii) The forecasting team was "***told to change***" ***the numbers*** (i.e., the internal forecasts) by Smith and Curran to conceal the lack of growth. ¶ 124.

(ix) According to FE 17, Defendants refused to lower the Otezla guidance per his warnings and instead put pressure on the salespeople to hit the impossible numbers. ¶ 127.

(x) FE 18 indicated that the aggressive Otezla guidance did not account for the introduction of new competition to the PA and psoriasis market and that CPMAC knew of, but simply ignored, this factor. ¶ 126.

(b) Multiple former employees confirmed that Defendants knew that 57% year-over-year growth in Otezla net product sales between 2016 and 2017 was unachievable.

(i) FE 19 stated that in late 2016, when Defendant Smith was assessing the 2017 Otezla market access information that FE 19's team put together and setting the sales targets, the market did not support anything close to the 57% growth Defendants told the public. ¶ 132. According to FE 19, there was no way Defendant Smith could have interpreted what his Market Access team was reporting and translated that into 57% sales growth for Otezla in 2017. ¶ 133.

(ii) FE 17 stated that as early as April 2016, the rebates due on existing Otezla prescriptions covered by "underwater" PBM contracts were "significant." ¶ 133. In light of these outstanding rebates, FE 17 stated that Celgene management should have given a warning to investors in the fourth quarter of 2016 because the IIEC knew about the rebate issue and the impact that it was going to have on the Company's 2017 Otezla revenues. ¶ 134.

(iii) In anticipation of a planned 2017 price increase for Otezla, Celgene's management acceded to the requests of many wholesalers to purchase in December 2016 the quantities of Otezla they were slated to purchase in January 2017, in order to take advantage of the lower price. ¶ 135. This

buy-in negatively and foreseeably impacted Otezla sales in the first quarter of 2017. ¶ 135.

(iv) FE 17 learned from Tessarolo that he had given a presentation to the IIEC in early 2017 concerning the disappointing Otezla sales and had warned the IIEC that the Company needed to downgrade its 2017 Otezla guidance. ¶ 137. However, rather than heed Tessarolo's warning, Defendant Smith cut him off, stating that he had heard enough of the negative information. ¶ 145.

(v) FE 7, added that "there isn't any way to grow [Otezla] revenue by 57%." FE 7 was very vocal to senior management and specifically told them that Otezla's growth could not continue because of the step-edit hurdles and the saturation of competitor drugs in the market. FE 7's warnings, however, were ignored. ¶ 136.

(c) Defendants lacked a reasonable basis for representing that new PBM contracts and the removal of step-edits would help the Company hit the 2017 Otezla sales guidance

(i) In November or December of 2016, FE 7 met with Grausso, Curran, Tessarolo, Swartz, Willcox and Owen and again warned these executives that paying to remove the step-edits for Otezla was not a cure for the drug's broad-based market access challenges. ¶ 143.

(ii) Even though the Company entered into new PBM contracts that went into effect in 2017, Celgene did not recognize revenues from prescriptions for many patients covered by these contracts until months later. ¶ 146. FE 18 stated that it was clear from the beginning of 2017 that the new PBM contracts were not meeting revenue expectations. ¶ 147. FE 18 communicated this fact to his boss, Swartz, and she reported this information to the CPMAC. ¶ 147. According to FE 18, notwithstanding the data showing that the contracts were underperforming, Celgene refused to lower expectations for the PBM contracts. ¶ 147.

(iii) FE 18 confirmed that the market for Otezla did not change rapidly in 2017: "We saw what was happening way before then. We had monthly meetings with the contract and pricing teams . . . very early on in 2017" and there was "worry" and "concern" at these meetings. As FE 18 further stated: "We were in trouble with our Otezla contracts. You heard that from a lot of the pricing and contract people." ¶ 151.

2. Ozanimod

282. Celgene's and the Individual Defendants' scienter with respect to the misstatements and omissions regarding the submission of the Ozanimod NDA and the status of

the Company's Ozanimod clinical development, is evidenced by the following facts, among others:

(a) Upon acquiring Receptos, Celgene exercised control and decision-making authority over Receptos and Ozanimod

(i) FE 20 explained that once Celgene agreed to acquire Receptos on July 14, 2015, all decisions were made by Celgene in New Jersey or on-site Celgene personnel. ¶ 158.

(ii) FE 21 stated that after the July 14, 2015 acquisition, Celgene did not allow Receptos' leadership to partake in any decisions that could potentially impact Celgene's stock price. ¶ 158.

(iii) FE 2 recalled that Martin, who FE 2 described as a "control freak" and Smith's right-hand man, was sent by Celgene to San Diego to serve as the Managing Director for Receptos. ¶ 159. FE 2 referred to Martin as the de facto chief executive of Receptos. ¶ 159.

(iv) FE 5 likewise described Martin as the CEO of Receptos after the acquisition and confirmed that Martin was in charge of the entire Receptos organization and reported directly to Smith. ¶ 159. FE 5 also recounted that Smith sent Gary Cline, Head of Strategic Research and Innovation, to San Diego to keep tabs on Ozanimod for him. ¶ 160.

(v) FE 22 further corroborated that Martin reported directly to Smith and Saillot was Martin's second in command. ¶ 160.

(b) Defendants knew that the Metabolite required additional testing prior to submitting the NDA, and that the NDA was deficient upon submission

(i) On November 21, 2016, Celgene completed the Mass Balance Study and identified the Metabolite. ¶ 183. FE 20 confirmed that the Metabolite was discovered during this study. ¶ 184. FE 21 similarly recalled that Celgene identified the Metabolite approximately one year before the Ozanimod NDA was submitted in December 2017. ¶ 184.

(ii) FE 21, who had first-hand knowledge of the Metabolite, discussed the discovery with Martin and noted that it was of great concern. ¶ 185. In response, Martin told FE 21 not to tell anyone about the Metabolite discovery and that Martin would tell him who needed to know and send people to him to work on the Metabolite. ¶ 185.

(iii) FE 21 stated that the employees in his role and Martin's role at Celgene knew about the Metabolite discovery. ¶ 185. FE 21 also stated that Celgene's senior leadership was briefed on the discovery of the Metabolite

and the ongoing characterization efforts "quite some time before the filing" of the NDA. ¶ 189.

(iv) FE 5 recalled that during an Ozanimod meeting in March or April of 2017, Tran confirmed the need for additional testing and studies of the Metabolite. ¶¶ 190-91. FE 5 confirmed that Martin, Saillot (who reported to Martin), Frohna (Vice President of Clinical Development and Translational Medicine, Receptos who reported to Martin), Kopicko (Executive Director of Biometrics, Receptos, who reported to Martin), Penenberg (Director, Receptos, who reported to Kopicko), Aranda (Vice President of Clinical Development, Receptos, who reported to Martin), Skolnick (Executive Director of Clinical Development, Receptos, who reported to Aranda), and others attended this March/April 2017 meeting. ¶ 190.

(v) FE 5 further recalled that at this March/April 2017 meeting Tran directed his comments concerning the Metabolite to Martin and Saillot, but that Martin and Saillot quickly shut down the conversation. ¶ 191.

(vi) FE 21 stated that he and his colleagues discussed the need to perform additional testing after finding the Metabolite and the working team in "clinpharm" advocated that if Celgene submitted the NDA, it would get a refusal to file. FE 21 confirmed that this was said to his direct management. ¶ 204.

(vii) FE 21 and his colleagues agreed that the Company should wait to complete testing on the Metabolite before submitting the NDA as there was no empirical reason to submit without it. ¶ 203. He was never provided any reason why Celgene was rushing to submit when it was clear that more work was required. When he expressed his feelings to his leaders he was told to keep his personal feelings to himself. ¶ 203.

(viii) According to FE 22, in November 2017, Celgene met with the FDA for a pre-NDA meeting. ¶ 207. FE 22 stated that during this pre-NDA meeting, the FDA told the Company: (i) the FDA needed the study results for the Metabolite; (ii) the results were very important; and (iii) the results had to be included in the Ozanimod NDA. ¶ 208.

(ix) As detailed above, ¶¶ 168-78, federal regulations and FDA guidance, which Defendants were required to follow, had a duty to monitor, and must have known about: (i) stress the importance of testing for metabolites before filing an NDA; (ii) require additional testing of metabolites where the results between human and animal testing differ; and (iii) mandate that NDAs address drug metabolism.

(x) Celgene's receipt of the RTF is additional evidence of Defendants' scienter because: (i) according to the FDA, "an RTF is based on omissions

of clearly necessary information (e.g., information required under the statute or regulations) or omissions or inadequacies so severe as to render the application incomplete on its face" (¶¶ 215-16); (ii) only 45 RTFs have been issued between December 31, 2001 and February 28, 2018 (¶ 217); and (iii) at least one market analyst noted that companies like Celgene "do not make execution mistakes like the one [involving the Ozanimod NDA]" (¶ 217).

(xi) Celgene admitted after the fact (in June 2018) that the NDA was facially deficient upon submission when it blamed Receptos for the NDA filing. ¶ 228.

(xii) FE 21, FE 22, and FE 2 all rejected the idea that the deficient NDA was submitted without the approval of Celgene's leadership, ¶¶ 230-31; and Hasnain, the former CEO of Receptos, and Frohna, the former Vice President of Clinical Development and Translational Medicine at Receptos, publicly stated that Celgene was responsible for filing the NDA. ¶ 229.

(c) Defendants were motivated to file the NDA for Ozanimod in late 2017 without the necessary Metabolite testing

(i) Defendants were motivated to submit the NDA in late 2017, rather than wait to complete the necessary Metabolite testing, because Gilenya was set to lose its patent exclusivity, paving the way for Gilenya generics that would compete with Ozanimod to enter the RMS market by the end of 2019. By submitting the NDA in late-2017 for early-2018 approval, Celgene sought to gain a year's worth of market share for Ozanimod before having to fend off cheaper competition from generics. ¶¶ 165-66.

(ii) Defendants also were motivated to hide the results of the Mass Balance Study, as they demonstrated that the Metabolite's half-life was much longer than Gilenya's, thereby wiping out a previously reported advantage of Ozanimod. ¶¶ 188, 211, 224.

(iii) Defendants also were financially motivated to submit the NDA in 2017. ¶ 212. FE 22 stated that both Martin and Saillot received bonuses for submitting the Ozanimod NDA by year-end 2017. ¶ 212. FE 20 confirmed that the compensation for the Celgene and Receptos personnel, including Martin, was tied to the Ozanimod NDA filing, and that the higher you went up the corporate chain, the greater the amount of compensation tied to the NDA filing. ¶ 212.

(iv) Celgene's annual proxy statement on Form DEF 14A, filed with the SEC on April 27, 2017, disclosed that Defendant Smith was entitled to performance awards based in part on the "filing of a new drug

application." ¶ 212. Smith received a lucrative performance award for 2017 of $629,125, along with company stock. ¶ 212.

B. THE I&I FRANCHISE WAS ONE OF CELGENE'S CORE OPERATIONS

283. Celgene's I&I franchise was one of the Company's core operations before and during the Relevant Period, and commercial stage Otezla and pipeline drug Ozanimod comprised the backbone of I&I during the Relevant Period. As discussed above (*see* ¶¶ 77-91), Celgene devised a three-pronged plan to develop and market three I&I drugs, GED-0301, Otezla, and Ozanimod, in an attempt to replace the Company's revenue stream from its extremely successful cancer drug, Revlimid.

284. The failure of the first prong, GED-0301, drastically increased the importance of the second and third prongs—respectively, Otezla and Ozanimod. Celgene described Otezla as its "***flagship product***" driving the I&I franchise's success. Indeed, Celgene noted that the Company was "dependent upon the continued commercial success of . . . Otezla." The third prong focused on Celgene's acquisition of Receptos and with it, Ozanimod, a development-stage drug that was described by one commenter as "the ***crown jewel*** of Celgene's $7.2 billion acquisition of Receptos, Inc." Following the Receptos acquisition, Celgene revised its 2020 revenue guidance for the I&I franchise up from $3 billion to over $4 billion. Based on the importance of the I&I franchise, and especially Otezla and Ozanimod, to Celgene's business, Defendants must have been aware of all material facts affecting their revenue generation potential.

285. Defendants' own statements confirm that they paid particularly close attention to the status of each drug. Throughout the Relevant Period, Defendants repeatedly acknowledged the importance of Otezla and Ozanimod to Celgene's success. For example, in announcing the Receptos acquisition, Celgene noted that its "I&I pipeline will, upon completion of the

[Receptos] transaction, consist of three high-potential commercialized or late-stage assets: OTEZLA, GED-0301 and Ozanimod." Celgene touted Otezla and Ozanimod as being among the Company's "multiple potential blockbuster products in I&I," which were the keys to replacing revenue when Revlimid lost its patent exclusivity:

- On July 23, 2015, Celgene touted Ozanimod and Otezla, as being among their "multiple potential blockbuster products in I&I" which were expected to lead the company towards "significant growth through 2020 and beyond."

- On September 12, 2016, Smith stated: "And then when you take a look at three of the next big programs for Celgene in terms of new products that are in late development right now, and sort of in time order coming up next would be ozanimod in multiple sclerosis, and the GED in Crohn's Disease. . . And then we've got ozanimod in UC. So, . . . we've got some major, major programs here to launch."

286. The repeated statements made by the Individual Defendants throughout the Relevant Period reaffirming the 2017 Otezla sales guidance and discussing the progress of Ozanimod toward NDA submission, strongly and plausibly suggest that each Defendant had detailed knowledge of or access to material facts and information misrepresented or concealed by Celgene's and the Individual Defendants' statements. In addition, the Individual Defendants' repeated statements regarding these topics demonstrate that these were areas upon which the Individual Defendants were particularly focused, had a duty to monitor, and therefore knew or recklessly disregarded the omitted and misrepresented information.

C. DEFENDANTS WERE FINANCIALLY MOTIVATED TO CONCEAL MATERIAL INFORMATION FROM INVESTORS

287. Defendant Curran, Celgene's President of Inflammation & Immunology, was financially motivated to commit securities fraud and realized substantial financial benefits from her personal sales of Celgene stock at the same time that she and the Company misrepresented and concealed from investors Celgene's material problems with Ozanimod and Otezla.

288. At the same time that Celgene issued materially false and misleading statements to investors, Curran collectively sold 30.56% of her Celgene stock on September 25, 2017, at the artificially inflated price of $143.89 per share, disposing of 1,727 shares for illegal insider trading proceeds of nearly a quarter-million dollars ($248,498).

289. Curran's sales of Celgene stock were suspicious in timing and amount. Curran's sale was suspiciously timed because it occurred after Curran and other senior executives had been warned that the 2017 Otezla sales guidance could not be met and should be lowered, but right before Celgene publicly disclosed the lowered guidance. Indeed, just weeks after Curran's September 25, 2017 stock sale, on October 26, 2017, Celgene disclosed sharply disappointing financial results for Otezla and lowered its financial guidance as a result. In response to that news, the price of Celgene stock fell to $99.99 on October 26, 2017. Curran's sale was suspicious in amount because on that single day, she sold 30.56% of the Celgene common stock she held at the time. A comparison of these sales to Curran's annual salary and bonus compensation is not possible at this time because her salary and bonus compensation is not publicly reported in Celgene Proxy Statements. In addition, a comparison of Curran's Relevant Period sales to her pre-Relevant Period sales is not possible at this time because her pre-Relevant Period sales are not publicly disclosed.

290. Celgene Form 4 filings with the SEC indicate that Curran's sale of Celgene common stock on September 25, 2017 was made pursuant to Rule 10b5-1 trading plans. However, those public filings do not specify when Curran entered into those plans. Accordingly, based on the currently-available record, it is quite likely that Curran entered into her Rule 10b5-1 plans governing this sale at a time when she was already in possession of material adverse non-public information, in which case her plan does not immunize her trades from securities liability.

291. At least one other high-ranking Celgene executive also engaged in suspicious trading during the Relevant Period. Hugin, Celgene's Executive Chairman, sold 275,970 shares of Celgene common stock during the Relevant Period at artificially inflated prices ranging from $120.00 to $134.14, for total proceeds of over $35.6 million and profits of at least $18.4 million. The cost basis of Hugin's sales of 100,000 shares of Celgene stock on November 9, 2016 is not publicly available, but Hugin's profits on just his sales of 175,970 shares of Celgene stock on June 22, 2017 alone are $18.4 million. Hugin's sales were suspicious in amount because his profits of at least $18.4 million from his June 2017 sales alone were approximately ***five times*** greater than his 2017 salary and bonus compensation ($3.675 million).

292. Hugin's June 22, 2017 sales of 175,970 Celgene shares were suspicious in timing for the additional reason they occurred at the time that: (i) Defendants knew that Celgene was not going to meet its 2017 Otezla sales guidance, but before the Company announced the shortfall on October 26, 2017; and (ii) Defendants knew that discovery of the Ozanimod Metabolite required extensive Phase I testing that would made it impossible to file a complete NDA in 2017, which materialized with announcements in February and April 2018 when the FDA rejected the Ozanimod NDA and the likely timetable for the missing Phase I testing was revealed, respectively. Moreover, Hugin's sales of 175,970 shares of Celgene common stock on June 22, 2017 were apparently ***not*** made pursuant to a Rule 10b5-1 trading plan, and are therefore particularly suspicious because, in contrast to his November 9, 2016 sales, Hugin made these sales outside of a pre-determined Rule 10b5-1 trading plan.

D. TERMINATIONS OF HIGH-RANKING PERSONNEL ARE PROBATIVE OF SCIENTER

293. The terminations and resignations of high-ranking executives, including Defendant Smith, during or shortly after the revelation of the alleged fraud, are further indicia of scienter.

294. In June 2017, while Celgene employees internally acknowledged that the Company was likely to receive an RTF in light of its decision to push ahead with the Ozanimod NDA submission without including the results from the additional Metabolite studies, Fouse, who made repeated statements regarding the timeline for Celgene's submission of the NDA, abruptly left Celgene. Fouse's departure came just a year after she was promoted to President and COO of Celgene.

295. Swartz, the Vice President of U.S. Market Access, was terminated in November 2017, one month after Celgene announced Otezla's failure to meet its 2017 guidance. As discussed above (*see* ¶ 129), Swartz was forced out due to her pushback regarding the unachievable 2017 Otezla guidance and Defendants' repeated fraudulent statements reaffirming this guidance.

296. Smith, who was promoted from President of I&I to COO in April 2017, abruptly resigned one year later, in April 2018. Smith's unexpected exit came just months after Celgene slashed its Otezla sales guidance, and disclosed that the FDA rejected Ozanimod's NDA for failing to provide the required data regarding the Metabolite.

297. Within a few weeks of Smith's resignation, George Golumbeski, Executive Vice President of Business Development, quietly resigned from his position on April 16, 2018. Notably, Golumbeski played a leading role in several of Celgene's acquisitions, including the acquisitions of Receptos (and Ozanimod).

VIII. THE FRAUD ON THE MARKET PRESUMPTION OF RELIANCE APPLIES

298. At all relevant times, the market for Celgene's common stock was efficient for the following reasons, among others:

(i) Celgene's common stock met the requirements for listing, and was listed and actively traded on the NASDAQ Global Select Market, a highly efficient and automated market;

(ii) As a regulated issuer, Celgene filed periodic public reports with the SEC and the NASDAQ Global Select Market;

(iii) Celgene regularly and publicly communicated with investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(iv) Celgene was followed by multiple securities analysts employed by major brokerage firms who wrote reports, which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace. Indeed, several hundred analyst reports on Celgene were published during the Relevant Period.

299. As a result of the foregoing, the market for Celgene's common stock promptly digested current information regarding Celgene from all publicly available sources and reflected such information in the price of Celgene's stock. Under these circumstances, all purchasers of Celgene's common stock during the Relevant Period suffered similar injury through their purchase of Celgene's stock at artificially inflated prices and a presumption of reliance applies. Further, at all relevant times, Plaintiff reasonably relied upon Defendants to disclose material information as required by law and in the Company's SEC filings. Plaintiff would not have purchased or otherwise acquired Celgene common stock at artificially inflated prices if Defendants had disclosed all material information as required. Thus, to the extent that Defendants concealed or improperly failed to disclose material facts with regard to the Company and its business, Plaintiff is entitled to a presumption of reliance in accordance with *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128, 153 (1972).

IX. THE STATUTORY SAFE HARBOR AND BESPEAKS CAUTION DOCTRINE ARE INAPPLICABLE

300. The Private Securities Litigation Reform Act's statutory safe harbor and/or the "bespeaks caution doctrine" applicable to forward-looking statements under certain circumstances do not apply to any of the materially false or misleading statements alleged herein.

301. None of the statements complained of herein was a forward-looking statement. Rather, each was a historical statement or a statement of purportedly current facts and conditions at the time each statement was made.

302. To the extent that any materially false or misleading statement alleged herein, or any portion thereof, can be construed as forward-looking, such statement was a mixed statement of present and/or historical facts and future intent, and is not entitled to safe harbor protection with respect to the part of the statement that refers to the present and/or past.

303. To the extent that any materially false or misleading statement alleged herein, or any portions thereof, may be construed as forward-looking, such statement was not accompanied by meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statement or portion thereof. As alleged above in detail, given the then-existing facts contradicting Defendants' statements, any generalized risk disclosures made by Defendants were not sufficient to insulate Defendants from liability for their materially false or misleading statements.

304. To the extent that the statutory safe harbor may apply to any materially false or misleading statement alleged herein, or a portion thereof, Defendants are liable for any such false or misleading statement because at the time such statement was made, the speaker knew the statement was false or misleading, or the statement was authorized and approved by an executive officer of Celgene who knew that such statement was false or misleading.

X. CAUSE OF ACTION

COUNT I
For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against Defendants Celgene, Smith, Curran, and Martin

305. Plaintiff repeats and realleges each and every allegation set forth above as if fully set forth herein.

306. This claim is brought by Plaintiff in connection with its purchases of Celgene common stock against Defendants Celgene, Smith, Curran, and Martin for violation of Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

307. As alleged herein, throughout the Relevant Period, Defendants Celgene, Smith, Curran, and Martin, individually and in concert, directly and indirectly, by the use of the means or instrumentalities of interstate commerce, the mails and/or the facilities of national securities exchanges, made materially untrue statements of material fact and/or omitted to state material facts necessary to make their statements not misleading and carried out a plan, scheme, and course of conduct, in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. Defendants Celgene, Smith, Curran, and Martin intended to and did, as alleged herein: (i) deceive the investing public, including Plaintiff; (ii) artificially inflate and maintain the prices of Celgene's common stock; and (iii) cause the investing public, including Plaintiff, to purchase the Company's common stock at artificially inflated prices.

308. Defendants Celgene, Smith, Curran, and Martin were individually and collectively responsible for making the materially false and misleading statements and omissions alleged herein and having engaged in a plan, scheme, and course of conduct designed to deceive the investing public, including Plaintiff, by virtue of having made public statements and prepared, approved, signed, and/or disseminated documents that contained untrue statements of material fact and/or omitted facts necessary to make the statements therein not misleading.

309. As set forth above, Defendants Celgene, Smith, Curran, and Martin made the materially false and misleading statements and omissions and engaged in the fraudulent activity described herein knowingly and intentionally, or in such a deliberately reckless manner as to constitute willful deceit and fraud upon the investing public, including Plaintiff, who purchased the Company's common stock during the Relevant Period.

310. In ignorance of the materially false and misleading nature of the statements and omissions made by Defendants Celgene, Smith, Curran, and Martin, and relying directly or indirectly on those statements or upon the integrity of the market price for Celgene's common stock, Plaintiff purchased the Company's common stock at artificially inflated prices during the Relevant Period, as set forth in Appendix A. But for the fraud, Plaintiff would not have purchased the Company's common stock at such artificially inflated prices. As set forth herein, when the true facts were subsequently disclosed, the price of Celgene's common stock declined precipitously, and Plaintiff was harmed and damaged as a direct and proximate result of their purchases of the Company's common stock at artificially inflated prices and the subsequent decline in the price of that stock when the truth was disclosed.

XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays for judgment as follows:

311. Declaring and determining that Defendants violated the Exchange Act by reason of the acts and omissions alleged herein;

312. Awarding Plaintiff compensatory damages against all Defendants, jointly and severally, in an amount to be proven at trial together with prejudgment interest thereon;

313. Awarding Plaintiff its reasonable costs and expenses incurred in this action, including but not limited to, attorneys' fees and costs incurred by consulting and testifying expert witnesses; and

314. Granting such other and further relief as the Court deems just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

LITE DePALMA GREENBERG & AFANADOR, LLC

Dated: April 16, 2020

/s/ Bruce D. Greenberg

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Counsel for Plaintiff

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is related to the following civil action:

- *Schwab Capital Trust, et al. v. Celgene Corporation, et al.*, 2:20-cv-3754 (J. Clark)

LITE DePALMA GREENBERG & AFANADOR, LLC

Dated: April 16, 2020

/s/ Bruce D. Greenberg

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